AN OPEN COMPARATIVE CLINICAL EVALUATION ON "VENPULLI (VITILIGO)" WITH SIDDHA TRIAL DRUGS "RASA CHENDHURAM" (INTERNAL) & "PALAGARAI KUZHAMBU" (EXTERNAL).

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **An open comparative clinical evaluation on Venpulli (Vitiligo) with Siddha Trial Drugs Rasa Chendhuram (internal) and Palagarai Kuzhambu (external)** is a bonafide and genuine research work carried out by me under the guidance of **Dr. M. MOHAMED MUSTHAFA, M.D (S),** Post Graduate Department of **Sirappu Maruthuvam**, Govt. Siddha Medical College, Arumbakkam, Chennai-106 and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

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CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **An open comparative clinical evaluation on Venpulli (Vitiligo) with Siddha Trial Drugs Rasa Chendhuram (internal) and Palagarai Kuzhambu (external)** is submitted to the Tamilnadu Dr.M. G. R. Medical University in partial fulfillment of the requirements for the award of degree of M.D (Siddha) is the bonafide and genuine research work done by **R.KALAI MANI** under my supervision and guidance. The dissertation has not formed the basis for the award of any Degree, Diploma, and Associate ship, Fellowship or other similar title.

Date: **Seal & Signature of the Guide**

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ENDORSEMENT BY THE HOD, PRINCIPAL/HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **An open comparative clinical evaluation on Venpulli (Vitiligo) with Siddha Trial Drugs Rasa Chendhuram (internal) and Palagarai Kuzhambu (external)** is a bonafide work carried out by **R.KALAI MANI** during the year 2014-2017 under the guidance of **Dr.M.MOHAMED MUSTHAFA, M.D (S),** Post Graduate Department of Sirappu Maruthuvam, Govt. Siddha Medical College, Chennai - 106.

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CONTENTS

INTRODUCTION

Siddha system of medicine is the traditional medical system of India which has flourished well before many centuries. Siddha is practiced till now rather than other traditional medical systems. In the wake of changing mode of life and modern medicine, Siddha continues to sustain its influence because of its incomparable intrinsic merits. This system was originated by siddhars with their holistic spiritual powers.

Agathiyar, Thirumoolar, Bogar, Theraiyar, Pulippani are the most remarkable siddhars. Agathiyar was the top most siddhar who is regarded as the originator of the Siddha medicine and also the Tamil Language. Siddhars are specialized in Vaatham,Vaithiyam, Yogam, Gnanam which helps to attain spirituality through prevent the body from disease, increase the lifespan by rejuvenation.

In India, five types of landscapes such as Kurinji, Mullai, Marutham, Neithal, Paalai contains many herbs helps to cure the disease of the people living there. Innumerable varieties of herbs, metals and minerals are mentioned in siddha literatures.

Siddha medicines are classified into Internal medicine thirty two types and External medicine thirty two types. The internal medicine starts as a simple preparations like saaru, kudineer, chooranam and ends in higher order medicines like kattu, kalangu, chunnam, Theeneer, chendhuram etc,.

Siddhars are alchemist who used metals and minerals in drugs for therapeutic effect. Mercury and other minerals are generally a poison for uninitiated but for the siddhars who knows how to detoxify it and pulverize it to nano ions, it is the nector of immortality. Chendhuram is one type of these internal medicine in siddha which is metallic substances or arsenical compounds are made into red coloured powders by the process of burning, frying or insulating or keeping them in specialized pudams by grinding them with decoctions, ceyaneer juices etc.

The size of particles present in higher order medicine are in nano level at the end of the process. So nano technology is the prime tool for siddha herbo-mineral drugs in which the medicine targets the affected spot and cures the disease. Nano medicines like chendhuram will scale down the number of doses and increases the bio availability. Siddha nano medicines will cure many chronic diseases with minimal side effects and with minimal drug dose which baffles and eludes even the modern sophisticated medicine.

Vitiligo is an acquired, idiopathic, depigmentory condition of skin and hair varying sizes and shapes. It affecting people of all ages and both sexes equally. Patients lose their skin color mostly in patchy and progressive manner.

The cause is still under debate. Although there are rarely physical symptoms involved many patients experience stigmatization, unwanted attention, negative comments, rejection or bullying. The prevalence of vitiligo is often said to range from 0.09 to 8% especially in India.

There are lot of drugs in our siddha system for Vitiligo. For the study, I selected the Rasa Chendhuram as internal medicine and Palagarai Kuzhambu as external medicine in the management of Vitiligo both in preclinical as well as clinical aspect.

AIM AND OBJECTIVES

AIM:

To evaluate the Siddha Drug Rasa Chendhuram (internal) and Palagarai Kuzhambu (external) in the management of Vitiligo.

OBJECTIVES:

Primary objective:

To evaluate the therapeutic efficacy of the siddha drug Rasa Chendhuram (Internal) and Palagarai Kuzhambu (External) in Venpulli (Vitiligo).

Secondary objectives:

- To study the safety profile of trial drug Rasa Chendhuram (Internal).
- The main objective of this study is to add the scientific evidences to Siddhars work which in turn create awareness among the public.
- To discuss the various literature evidences of Venpulli in Siddha Medicine and Vitiligo in modern science.
- To correlate the clinical features of Venpulli in Siddha medicine with Vitiligo in modern science.
- To correlate the modern purification method and siddha purification method of raw drugs.
- To get the authentication of the raw drug.
- To standardize the standard operating procedure.
- To study the Physico - Chemical analysis of the selected trial drug.
- To study the acute & sub acute toxicity of the trial drug Rasa Chendhuram according to OECD guidelines.

REVIEW OF LITERATURE

SIDDHA ASPECT

Synonyms:

Venkuttam

Swetha Kuttam

Venthittu

Venpadai

Definition :

Venpulli is defined as the discoloration of the skin characterized by the appearance of the white patches in irregular shape of the epidermis of the skin and sometimes hair also involved.

In siddha system venpulli is considered as one of the eighteen kinds of kuttam. Siddhar Yugimuni mentioned this condition as Suvetha Kuttam in *"Yugimuni Vaithiya Chinthamani – 800"*.

தடிப்பாக தவள நிறம் போல் வெளுத்துச்
சர்வாங்கமும் வெளுத்தாற் றான்றிரும்பும்
மடிப்பாக மயிர்வெளுத்தா லசாத்ய மாகும்
வரிவுதடு வுள்ளங்கை குதங்குய்யந்தான்
நெடிப்பாக நெருப்பு பட்டது போல புண்ணாய்
நிறமிருந்தா லசாத்தியமென்றே யுரைக்கலாகும்
வெடிப்பாக மேனியெல்லாம் வெளுத்து வீங்கி
வெண்சுவேத குட்டமென்றே விளம்பலாமே.

- Hypopigmented patches all over the body.
- Hypopigmentation on hair, lips, palm, sole, anus and pubic region –incurable.
- If the lesion is like burnt scar- incurable.

நோய் வரும் வழி: (Aetiology)

According to siddha system, the predisposing causes for this diseases have been described as hereditary factor, stress and strain, malnutrition and venereal exposure and no other specific causes have been mentioned for venpulli.

1) **According to Agathiyar Kanma Kandam**

"சேர்ந்தகுட்ட மோடுகுறை நோய்கள் வந்த
சேதிகள் மலராதவரும்பு கொய்தல்
தாரிந்த சீவசெந்து வதைகள் செய்தல்
தாய் தந்தை மனதுநொந்தது ரோகந்தானே"
தானென்ற தெய்வவுருத் தனையழித்தல்
சார்வான பெரியோர்கள் தமைப் பழித்தல்
கானென்ற நந்தவனம் பூஞ்செடிகள் வெட்டல்
கருமமடா சரீரத்திற் காசு போலே
யூனென்ற வுடம்பெல்லாம் மொட்டுப் பொட்டா
யுடன் வெளுத்து குறைநோயா யுதிரஞ்சிந்தும்
வானென்ற கருமங்கள் தீர்ப்பதற்கு
வகையொன்று சொல்வேன் கேள் நந்தவனம்வையே

அகத்தியர் கன்ம காண்டம் கௌமதி நூல் பக்கம் - 27

Agathiyar kanmakandam says that picking flowers before blossoming, killing living creature, giving sorrow to the parents, destroying temples, abusing noble person, cutting plants cause Venpulli noi.

2) According to Thirumoolar Karukkidai Vaithya Nool

"வியாதியுண் மூவாறு விளங்கிய குட்டங்கேள்
சுயாதிக் கிரந்தி சுழன் மேகத்தாலாறும்
பயாதி மண்ணுளப் பலவண்டினா லெட்டும்
நியாதிப் புழுநாலாய் நின்றதிக் குட்டமே."

Six types of kuttam i.e, skin diseases are caused by kiranthi and megam, eight types are caused by insects in the soil, and four types are caused by worms.

3) According to Dhanvanthri vaidhyam

"அறிவின்றி விபரிதஞ் சேராகாரம் புசிக்கலாலும்
துறையன்றி தொடாத தொன்றை தொட்டவைப் புசிக்கலாலும்
. . . .
வந்திந்துப் பூருவா சென் மாந்திர பாவத்தாலுஞ்
சந்திக்கக் கற்புமாதர் தங்களைக் கருதலாலும்
தொந்தித்த குட்டரோகந் தொடுக்குமென்றுரைத்தார் முன்னோர்."

4) According to Dhanvanthiri Vaidhyam

- Intake of unhygienic food
- Abusing the elderly people like Siddhars and saints.
- Blaming the worshipping ladies.
- Sins committed in the previous birth.
- Thinking of seducing chaste women. These are the causes mentioned by Dhanvanthiri.

5) According to "Guru Naadi Nool''

"கிருமியால் வந்ததோடம் பெருக வுண்டு
கேட்கவதின் பிரிவதனைக் கிரம மாக
பொருமிவரும் வாயுவெல்லாம் கிருமி யாலே
புழுக்கடி போல் காணுமது கிருமியாலே
செருமிவரும் பவுத்திரங்கள் கிருமியாலே
தேகமதில் சோகைக்குட்டங் கிருமியாலே
துருமிவருஞ் சுரோணிதங் கிருமியாலே
சூட்சமுடன் கிரிசைப்பால் தொழில்செய் வீரே".

கிருமியால் உண்டாகும் குட்டம் வரலாறு[8]

"குட்டமது விடகரப்பான் விடநீர் சூலை
சுரோணிதத்தால் தாதுகெட்டுத் தடிப்புண்டாகும்
மட்டறமே கிருமிசென்று மருவும் போது
வகையாய்க் கிருமியுட விடநீர் சென்று
குட்டமுடன் தேகமெல்லாம் பறக்கும் போது
குழிகுழியாய்க் கிருமியினீக் கொள்ளும் புள்ளி
தட்டறவே கிருமியுட நீரால்வந்த
சகலகுட்டம் விடகரப்பான் சாற்ற லாமே."

5) According to "Siddha Maruthuvam Sirappu"

The etiology and the characters of Venpulli are clearly explained in the text **"**Siddha Maruthuvam Sirappu**"** as follows:

In the affected area, reduction or total loss of skin pigment melanin on the epidermis is observed. As the distinct aetiology is not known, there exist certain beliefs and hypothesis about the disease. They are

- Constant irritation to the skin owing to clothes, rubber, plastics or other chemical substances.
- Some essential metal or mineral deficiency in the food

6. According to "Eighteen Siddhars Naadi Nool"

Excessive intake of acidic food stuffs leads to pallor and discolouration of skin are the cause for vitiligo said by Pathinen Siddhar Naadi Nool.

7. According to "Agathiyar Vaithyam"

குயல்வாய் குஷ்டம் சயங்குன்ம நீரிழிவு சுரக்கிராணி
நீரடைப்பு பாண்டு மூல வாய்வு
கயல் வாயு வருங்கண்ணில் குத்தாய் கடிந்த தசவாய்வு
காணவாக முன் செய்த உயிர்களும் வினைதானே

Kuttam may be hereditary, apart from all other etiological factors Kuttam is also considered to be followed by Sins committed in the previous birth (Kanma vinai).

CLASSIFICATION:

1) According to yugi vaithiya chinthamani:

In "*Yugimuni Vaithiya Chinthamani – 800"*, Kuttam is classified into eighteen types. Swetha Kuttam (Venpulli) is one among them. It is mentioned as below:

"முத்தாகும் குட்டந்தான் பதினெட்டுக்கும்
முனியான யூகினான் சொல்லக் கேளாய்
புத்தாகும் புண்டரீக குஷ்டத்தொடு
பெருகின்ற விற்போடகக் குட்டமாகும்
பத்தாகும் பாமா குஷ்ட ஏகசர்ம குஷ்டம்
பரிவான கர்னகுஷ்டம் சர்மகுஷ்டம்
கித்தாகுங் கிருஷ்ண குட்டம் அவுதும்பர குட்டம்

கேடியான மண்டல குஷ்டமாகு மென்னே
குட்டமா மபரிச குஷ்ட மோடு
மருவலாங் கிடிப குஷ்டந் சர்மதல குஷ்டந்
திட்டமாற் தத்துரு குஷ்ட மோடு
தக்கான சித்துமா குஷ்டஞ் சதாரு குஷ்டந்
துட்டமாஞ் சுவேத குஷ்டதன் னோடொக்கச்
சுயம்பான பதினெட்டு குட்டமாச்சே.

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1.Pundareeka Kuttam

2.Virpodaka Kuttam

3.Baama Kuttam

4.Gaja Saruma Kuttam

5.Karna Kuttam

6.Siguram

7.Krishna Kuttam

8.Avudhumbaram

9.Mandala Kuttam

10.Abarisa Kuttam

11.Visarchika Kuttam

12.Vibaathika Kuttam

13.Kideeba Kuttam

14.Sarmathala Kuttam

15.Thethru Kuttam

16.Sithumaa Kuttam

17.Sathaaru Kuttam

18.Swetha Kuttam

2) According to "siddha maruthuvam sirappu"

Venpadai has been classified into four types :

1.vaatha venpadai

2.piththa venpadai

3.kabha venpadai

3) According to athma rakshamirtha vaidhya sarasankiraham

Kuttam is classified into 4 types

1. Venkuttam
2. Senkuttam
3. Karunkuttam
4. Peru viyathi

4) According to "Pararasa Sekaram"

Kuttam is classified into 5 types:

1. Venkuttam
2. Senkuttam
3. Karunkuttam
4. Vishakuttam
5. Azhukannikuttam

5) A classical work "Madhava Nithanam" classifies Venpulli noi as

1. Savithram
2. Kilesam
3. Varunam

6) According to siddhar aruvai maruthuvam

Venpadai has been classified into 3 types on the basis of mukkutram, they are,

1. Vaatha venpadai
2. Piththa venpadai

CLINICAL FEATURES :

1) According to "Yugimuni Vaithiya Chinthamani – 800"

Yugimuni attributed the Venpulli under the headline of Swetha Kuttam which is one of the eighteen kuttams and he mentioned the clinical features of swetha kuttam as below:

தடிப்பாக தவள நிறம் போல் வெளுத்துச்
சர்வாங்கமும் வெளுத்தாற் றான்றிரும்பும்
மடிப்பாக மயிர்வெளுத்தா லசாத்ய மாகும்
வரிவுதடு வுள்ளங்கை குதங்குய்யந்தான்
நெடிப்பாக நெருப்பு பட்டது போல புண்ணாய்
நிறமிருந்தா லசாத்தியமென்றே யுரைக்கலாகும்
வெடிப்பாக மேனியெல்லாம் வெளுத்து வீங்கி
வெண்சுவேத குட்டமென்றே விளம்பலாமே.

Yugimuni gives a clear definition of Venpulli and he mentioned the conditions which will not responded to treatment (Asathiyam) as said below:

1. Whitish discoloration of the part of the body or entire body. Sometimes hair also turns white.
2. When white patches occur on the palms or muco-cutaneous junctions like lips, anus and genitals, it is said to be rarely curable.
3. If the hair becomes white, prognosis will be very bad.
4. Fissured body becomes oedematous.

2) According to thanvanthiri vaithiyam

மீக்கௌத் தோறூமெலுமோர் முகம் வெளுக்குமாகில்
நோக்கியல் மரிக்குஞ் சொன்ன வெண்குட்டமாமே.

When the colour of the face becomes white, it is called Venkuttam.

3) According to Vaithya Sarasangiragam

Sole, hands, lips, scalp, fingers and wrist joint all these organs are found with white coloured patches which are circumscribed along with thickened border and gradually spread which is known as venpulli . blood, muscle and adipose tissue are affected by disease.

Discolouration of hairs, absence of normal skin texture when compared with the adjoining normal skin area and appearance of burn scar is incurable.

Premonitory symptoms:

1. The skin appears glittering and rough
2. There is an excessive perspiration or no perspiration
3. Discoloration
4. Heat and itching of the skin
5. Numbness in some parts of the body.

4) According to Pararasa Sekaram

1. Watery discharge
2. Grey colour
3. Foul smelling
4. Dryness of the scalp

5) A classical work **"Madhava Nithanam"** classifies Venpadai as

- Savithram – venpulli affecting muscular tissue.
- Kilesam - venpulli affecting the skin.
- Varunam - venpulli affecting the adipose tissue.

These types are not having any pathological discharge.

Kilesam is classified on the basis of mukkutram and their features are as follows:

- Vaatha kilesam - Reddish white in colour.
- Piththa kilesam - Red coloured patches resembling the petal colour of lotus.
- Kaba kilesam - milky thickened white patches with itching.

6) According to anubhava vaithiya deva ragasiyam

இந்நோயை குஷ்டமென கூறினும் இது குஷ்ட வகைகளின்று வேறுபட்டது என்பதையும் குஷ்டத்தைப் போல் அவ்வளவு கொடுமையான வியாதி அல்லவென்றும் உணரவேண்டும். இந்நோயில் திட்டு திட்டாக வெண்மை நிறமான படைகள் உண்டாகி பிறகு தேகம் முழுவதும் பரவி உடலை விகாரப்படுத்துதல் முதலிய குணங்களை உடையது.

Three types

1. Vatha venpadai
2. Piththa venpadai
3. Kaba venpadai

CLINICAL FEATURES

1. The skin appears glittering and rough
2. There is an excessive perspiration
3. Discolouration
4. Heat and itching of the skin
5. Numbness in some parts of the body

According to Sirappu Maruthuvam

1. Vaatha Venpadai
2. Piththa Venpadai
3. Kaba Venpadai
4. Mega Venpadai

1. VAATHA VENPADAI

It is characterized by the presence depigmented patches ,which are dry ,rough, reddish or pale black in colour.

2. PITHA VENPADAI

It is characterized by the presence of depigmented patches which are red in colour like lotus flower, spreading with burning sensation and loss of hairs on that area.

3. KABA VENPADAI

It is characterized by the depigmented patches which are white in colour like leucas flower spreads with rashes and itching .

4. MEGA VENPADAI

It is due to the veneral disease and it occurs after 4 or 6 months after the onset of disease, syphilis within four or six months of the attack. This venpadai develops initially along the nape and the adjoining spaces. Also gradually it affects the shoulder joints, back of trunk .

Clinical features of this type

Depigmented patches are small in number. Pale in colour, turmeric colour or dark colour margin marked with hyperpigmented signs. These lesion are circumscribed with 2mm to 3mm diameter or above. This correct picture of hypopigmented and hyper pigmented skin seems to be more or less a multi eyed filter (sieve–like) Females are more prone to this mega venpadai, therefore anti –syphilitic therapy is mandatory in the early period of the treatment.

CHARACTER OF VENPADAI

Skin color will change to reddish black or reddish white or white colour with spreading nature. The imbalance of the three thathu produces certain lesions in skin known as kuttam. Absence of perspiration and thickening of skin may produce the colour changes in skin.

தீரும், தீராதவை

1) ACCORDING TO DHANVANTHIRI VAITHYAM

சாத்தியம்-11

பூண்டந் நுரவினோடு சதாரிகம் புண்டரீ கந்த
தாண்டு விற்போடம் பாமாவுடன்மைதலம் வெண்குட்டம்
கூண்டிடு காகறந்தி சிறுமை யசல குட்டம்
வேண்டியவியாதியோடும் பதினொன்றும் விரித்துக் கானே. (Page No : 325)

அசாத்தியம்

சொல்லுகுட்டம் ஏழுவகைபேர் சொல்லிக் கபால சர்மீகம்
வெல்லு முதும்பா மேகிடிபம் விசர்ச்சிமண்டலக் கிரமும்
மல்லல் தருமீசி யகுவை யாகும் பெயரோ ழாகும்
வல்லகியாதிக் குணமதனை வகுத்துப் பாரிலுரைரைப்பேனே"

CURABLE-11

1. Thethru Kuttam
2. Sadhaaru Kuttam
3. Pundareega Kuttam
4. Virpodaga Kuttam
5. Sarmathala Kuttam
6. Baama Kuttam
7. Kaha Nandhi
8. Venkuttam
9. Sithuma Kuttam
10. Alasa Kuttam
11. Vibaathiga Kuttam

INCURABLE -7

1. Kabaala kuttam
2. Sarumamega kuttam
3. Kideeba kuttam
4. Avudhumbara kuttam
5. Visarchika kuttam
6. Aguvai kuttam
7. Mandala kuttam

ACCORDING TO YUGI CHINTHAMANI-800

குட்டந்தான் பதினெட்டில் சாத்தியந்தான்
கூறக்கேள் விற்போடக பாமா குட்டம்
திட்டந்தான் கெசசர்ம குட்டமொடு
கிருட்டிண குட்டமவுதும்பர குட்டந்தானும்
திட்டமாந் தேத்துருக் குட்டமொடு
செய்சித்துமா குட்டங் கிடிப குட்டம்
தட்டந்தான் மிகுந்தச தாரு குட்டம்
சமகிருட்டிண குட்டம்சாத் தியமா மென்னே" (Page No:200)

CURABLE

1. Virpodagam kuttam
2. Baama kuttam
3. Gaja Saruma kuttam
4. Krishna kuttam
5. Avuthumbara kuttam
6. Thethuru kuttam
7. Sithuma kuttam
8. Kideepa kuttam
9. Sathaaru kuttam
10. Sarmathala kuttam

INCURABLE

1. Pundareeka kuttam
2. Karna kuttam
3. Sikura kuttam
4. Mandala kuttam
5. Abarisa kuttam
6. Visarchika kuttam
7. Swetha kuttam
8. Vibathika kuttam .

2) According to the text "Siddha Maruthuvam Sirappu"

Curable conditions in Venpulli are:

Lesions without any change in hair colour.

Lesions without coarse texture.

Lesions that are not appearing like white burnt scar.

Uncurable conditions in Venpulli are:

Lesions with whitened hair.

Lesions feeling rough.

Lesion appearing like white burnt scar.

If the lesion first appears on genitalia, anus palms and lips.

Lesions of fast spreading nature.

SIDDHA PATHOLOGY:

Disease occurs due to the derangement in

- muththathukkal
- seven Udal thathukkal
- Kaala marupadukal (seasonal changes)
- Thinai (living lands) and
- Udal vanmai.

Muththathukkal

The function of the three uyir thathus:

a) Vali – Kattru + Veli
b) Azhal – Thee
c) Iyyam – Neer + Mann

The alteration of three thathu in their reaction to extrinsic or intrinsic factors results in disharmony. This altered harmony and balance variation of the three thathus results in disease. Their natural ratio (1:1/2:1/4) to each other is discerned by the physician at the wrist and each nadi is individually assessed for its strength, speed and regularity.

VATHAM

The term vatham denotes vayu, dryness, pain and flatulence , sensitiveness, lightness and also air. Based on functions and locations it is classified into ten types.

1. Piranan

(Uyirkkaal)

Responsible for respiration and it is necessary for proper digestion.
In venpulli noi pranan is normal.

Abanan (Keel nokkukkaal)

Responsible for all the downward forces such as voiding of urine, stools, semen, menstrual flow.
In venpulli noi abanan is normal.

Viyanan(Paravukaal)

Dwells in the skin and is concerned with the sense of touch, extension and flexion of the parts of the body and distribution of the nutrients to various parts of the body.
In venpulli noi viyanan affected. (skin color changed into white).

Uthanan (Melnokkukaal)

Responsible for all kinds of upward motion such as nausea, vomiting etc.,
In venpulli noi uthanan is normal.

Samanan(Nadukkaal)

Considered essential for proper digestion, assimilation and carries the digested nutrients to each and every organ.
In venpulli noi samanan is normal.

Nagan

Helps in opening and closing of eyelids.
In venpulli noi nagan is normal.

Koorman

Responsible for vision, lacrimation and yawning.
In venpulli noi koorman is normal.

Kirugaran

Induces appetite, salivation, all secretions in the body including nasal secretion and sneezing.
In venpulli noi kirugaran is normal.

Thevathaththan

Induces and stimulates a person to become alert, get anger, to quarrel, to sleep etc.,

In venpulli noi thevathathan is normal.

Dhananjeyan

Resides in the cranium and produces bloating of the body after death. This leaves from the body after 3 days of death, forming a way through the skull.

In venpulli noi dhananjeyan is normal.

PITHAM

It is the thermal life force of the body. It is sub divided into five types. They are

Anarpitham

Peps up the appetite and aids in digestion.

In venpulli noi anarpitham is normal.

Ranjagapitham

Responsible for the colour and contents of blood.

Ranjaga pitham affected in venpulli noi.

Saathagapitham

Controls the whole body and is held responsible for fulfilling a purpose.

In venpulli noi saathaga pitham is normal.

Pirasagapitham

Dwells in the skin and concerned with the shine, glow, texture and its complexion.

In venpulli noi prasaga pitham is affected.

Alosagapitham

Responsible for the perception of vision. In venpulli noi alosaga pitham is normal.

KABAM

It is responsible for the stream line functions of the body and maintains body's defence mechanism intact. It is again classified into 5 types.

Avalambagam

Lies in the respiratory organs, exercises authority over other kabhas and control the heart and circulatory system.

In venpulli noi avalambagam is normal.

Kilethagam

Found in stomach as it seat, moistens the food, softens and helps to be digested.

In venpulli noi kilethagam is normal.

Pothagam

Responsible for the perception of taste.

In venpulli noi pothagam is normal.

Tharpagam

Presents in the head and is responsible for the coolness of the eyes, sometimes may be referred to as cerebrospinal fluid.

In venpulli noi tharpagam is normal.

Santhigam

Necessary for the lubrication and the free movements of joints **.**

In venpulli noi santhigam is normal.

PARUVAKALAM MAARUBADUKAL :

With reference to the position of the sun in the orbit, the years divided into six seasons .

They are,

Perum pozhuthugal

1) Kaar kaalam

(Aavani & Purattasi)

Mid August to Mid October

Mukkutra marupaadugal

VATHAM - Vaetrunilai valarchi

PITHAM – Thannilai valarchi

Perum pozhuthugal

2) Koothir kaalam

(Iypasi & Karthigai)

Mid October to Mid December

VATHAM – Thannilai adaidhal

PITHAM - Vaetrunilai valarchi

Perum pozhuthugal

3)Munpani kaalam

(Margazhi & Thai)

Mid December to Mid February

PITHAM – Thannilai adaidhal

Perum pozhuthugal

4)Pinpani kaalam

(Masi & Panguni)

Mid February to Mid June

KABHAM – Thannilai valarchi

Perum pozhuthugal

5)Elavenir kaalam

(Chithirai & Vaikaasi)

Mid April to Mid June

KABHAM – Vaetrunilai valarchi

Perum pozhuthugal

6) Mudhuvenir kaalam

(Aani & Aadi)

Mid June to Mid August

VATHAM – Thannilai valarchi

KABHAM – Thannilai adaidhal

In every season there will be changes in the land, water, plants, animals and human beings , which will modify the physiology and making (rendering) them susceptible to certain specific disease which are common in these seasons. The siddhars have been anticipated those changes and advised certain measures in the form of diet, purgative, etc

THINAI (LAND)

Siddhars classified the lands into five types. They are

1. Kurunji – Mountain range
2. Mullai – Pastoral area of the forest
3. Marudham – The fertile river bed
4. Neidhal – The coastal region
5. Paalai – Arid desert

- Kabha diseases will occur in Kurinji land. Pitha diseases occur in Mullai land. Vadha diseases occur in Neidhal land. Staying in Paalai land is not good to health. Marudham land is the fertile area where no disease occurs. So, Marudham land is the best one to stay in.

The winter season gives good health to the man, early summer and later rainy gives moderate health. Whereas early rainy and later summer are more prone to diseases, that's why siddhars called it as Aanadha kaalam.

RELATION BETWEEN MUKKUTRAM, KAALANGAL AND THINAIGAL

Mukkutram	Paruvakaalam (Seasons)			Thinai
	Thannilai valarchi (Accumulation)	**Vaetrunilai valarchi (Aggravation)**	**Thannilai adaidhal (Alleviation)**	
VATHAM	Mudhuvenil kaalam	Kaar kaalam	Koothir kaalam	Vatha disease is more prevalent in Neidhal land
PITHAM	Kaar kaalam	Koothir kaalam	Munpani kaalam	Pitha disease is more prevalent in Mullai land
KABHAM	Pinpani kaalam	Elavenil kaalam	Mudhuvenil kaalam	Kabha disease is more prevalent in Kurunji land

UDAL VANMAI (IMMUNITY)

Siddhars classify udal vanmai into three types. They are

1. Iyarkai vanmai
2. Kala vanmai
3. Seyarkai vanmai

UDAL KATTUGAL

S.No	Udal kattugal	General Features	Changes in venpulli
1	Saaram (Digestive essence)	Responsible for the growth and development. It keeps the individual in good temperament and it enriches the body.	affected
2	Senneer (Blood)	Responsible for the color of the blood and for the intellect, nourishment, strength of the body.	Affected

3	Oon (Muscle)	Gives lookable contour to the body as needed for the physical activity. It feed the fat next day and gives a sort of plumpness to the body.	Normal
4	Kozhuppu (Fat)	Lubricates the organs to facilitate frictionless functions.	Normal
5	Enbu (Bones)	Supports and protects the vital organs, gives the definite structure of the body and responsible for the posture and movements of the body.	Normal
6	Moolai (Bone marrow)	Nourishes the bone marrow and brain which is the centre that controls other system of body.	Normal
7	Sukkilam/Suronitham (Sperm/Ova)	Responsible for reproduction[30].	Normal

PINIYARI MURAIMAI (DIAGNOSIS)

Four steps are followed in diagnosing the disease. They are

1. Poriyaal aridhal
2. Pulanal therdhal
3. Vinaadhal
4. Envagai thervugal

PORIYAAL ARIDHAL:

In this, the physician should carefully observe the changes that occur in the five sensory organs (porigal) of the patient.

PULANAL THERDHAL:

The physician carefully applies his five senses of perception, smell, taste, vision, touch and sound to understand the condition of the patient.

VINAADHAL:

The physician should interrogate about the patients name, age, occupation, socio-economic status, food habits, history of past illness, history of present illness, family history, marital status, menstrual history and frequency of pain.

ENVAGAI THERVUGAL:

நாடிப்பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவராயுதம்

noi nadal noi mudhal nadal thirattu, part-i (pg no-270)

Nowadays advanced diagnostic tools have been developed by modern bio medical scientists. But siddhars have given eight diagnostic methodological tools. They are called as Envagai thervu.

Eight fold system of clinical assessments:

Siddhars have given eight diagnostic methodological tools. They are

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram

GENERAL FINDINGS:

NAADI:

Naadi is responsible for the existence of life, can be felt one inch below the wrist on the radial side by means of palpation with tips of index, middle and ring finger, corresponding to vatham, pitham, kabham.

Three humours Vatham, Pitham, and Kabham are in the ratio 1:1/2:1/4 normally. Derangement in these ratio leads to various disease conditions.

Naadi in venpulli

Vathapitham or pitha kabam

SPARISAM:

By sparisam, the temperature of skin (thatpam- cold or veppam – heat), smoothness, roughness, sweating, dryness, hard patches, swelling, abnormal growth of organs and tenderness can be felt.

In venpulli – hypopigmented patches present.

NAA:

Signs and symptoms in the tongue are noted here. Colour, salivary secretion, ulcers, coating, inflammation, taste changes, deviation and its nature are generally noted.

- In venpulli in anaemic conditioned tongue may be pallor.

NIRAM:

The colour of the skin is noted here.

- In venpulli – the natural skin color become white.

MOZHI:

Character of the speech is noted, mainly uraththa oli (high pitched), thazhndha oli (low pitched), or resembles the sound of any instrument.

- In venpulli no changes in voice.

VIZHI:

Character of the eye is noted. Colour, warm, burning sensation, irritation, visual perception are generally noted.

- In venpulli no changes in vizhi.

MALAM:

The stools are examined for quantity, hardening (malakattu), loose motion (bedhi), colour and smell.

- In venpulli no changes.

MOOTHIRAM:

a) NEERKURI (Urine examination)

Urine examination is good diagnostic method compare to naadi and other Envagai thervugal. Theraiyar mention it as.

“அருந்துமாறிரதமும் அவிரோதமதாய்
அஃகல் அலர்தல் அகாலவூண் தவிர்ந்தழற்
குற்றளவருந்தி உறங்கி வைகைறை
ஆடிக்கலசத் தாவியே காது பெய்
தொருமுகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே”

noi nadal noi mudhal nadal thirattu, part-i (pg no-282)

The early morning urine sample is collected and sample should be examined within one and hour hours.

SIRUNEERIN POTHU GUNAM:

“வந்த நீர்க்கரி எடை மணம் நுரை எஞ்சலென
றைந்தியலுளவை யறைகுது முறையே”

noi nadal noi mudhal nadal thirattu, part-i (pg no-282)

The urine is examined for its Niram (colour), Eadai (Specific gravity), Nurai (Froth), Natram (Smell), Enjal (Deposits).

NIRAM (COLOUR)

NIRA THOGAI

“பீதம் செம்மைபைங் கருமை வெண்மையென்று
றோதைங்கொழுமையை யொத்துகு நீரே”

noi nadal noi mudhal nadal thirattu, part-i (pg no-283)

1. Yellow
2. Red
3. Green

4. Black
5. White

Urine may be any colour as mentioned above.

EADAI (SPECIFIC GRAVITY)

Urine, not thick is considerably healthy. This is mentioned as

“மிகத் தடிப்பும் மிகத் தேறலும் இன்றெனில்
சுகத்தை தரும் மெய்ச் சுபாவ நீர் நன்றே”

noi nadal noi mudhal nadal thirattu, part-i (pg no-294)

NURAI (FROTH)

Urine may be frothy in nature, if it is reduced in vali, azhal and ayyam are said to be deranged. This is mentioned as

நுரைதேய்த் தொழுகு நீர் நுவலுரும் மும்மலம்
கரைய இளகிடும் காலத் தென்னே”

noi nadal noi mudhal nadal thirattu, part-i (pg no-296)

NAATRAM (SMELL)

Foul odour with pyuria is observed in patients with urinary lithiasis associated with urinary tract infection and ulcer. This is mentioned as

“வெய்ய துர்க்கந்தம் வீசுநீர் மூத்திரப்
பைநாளமிவற்றைப் பற்று புண்குறியே
அம்மொழியின் றெனினனிலமே முதலிய
மும்மலச் சுதமே மூலமென் றுணரே.”

noi nadal noi mudhal nadal thirattu, part-i (pg no-294)

ENJAL (DEPOSITS)

If urine excretion look like curd water white colour and sand like deposits in urine indicate stones in kidney. This is mentioned as

“நார்த்ததி நீரைபோல நவையுற்றங் கிழியுமானால்
மாரற்ப முற்றநீரி லடிமண்டிக் கிடந்த தானால்
பாரிந்த மெழுகுமாங்காய் பற்றிய கல்லினாலே
சீருற்ற செய்கையென்று தெறிவுறச் செப்பலாமே”

noi nadal noi mudhal nadal thirattu, part-i (pg no-321)

NEIKURI

The early morning urine of the patient is analyzed by dropping a drop of gingely oil on the surface of the urine sample. The accumulation, formations, changes, and dispersal under the sunlight without any external disturbances of the urine sample can be noted.

The urine kept on the kidney tray in sun light, on non wind condition, should be examined by dropping a drop of gingili oil gently with rod. If oil spread like snake, it indicates vali neer; a ring indicates azhal neer and float like a pearl indicates iyya neer and sinks in urine indicates mukkutram.

“அரவென நீண்டினஃகே வாதம்
ஆழி போற்பரவின் அஃதே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே”

noi nadal noi mudhal nadal thirattu, part-i (pg no-298 - 299)

- Vatha neer – The oil spreads like snake
- Pitha neer – The oil spreads like ring
- Kabha neer – The oil spreads like pearl
- If the oil spreads gradually, it indicates good prognosis
- If the oil spreads fast or gets mixed completely with urine or sinks in urine, it suggests bad prognosis.

MODERN ASPECT

Dermatology is the branch of medicine dealing with both normal and abnormal skin and associated structures such as hair, nails, and oral and genital mucous membranes.

IMPORTANCE OF DERMATOLOGY

- ✓ Skin diseases are very common, affecting up to a one third of the population at any one time.
- ✓ Skin disease is often easily noticeable than other disease so this is a cause of great social concern to the patient.
- ✓ Skin diseases have serious impacts on life. They can cause physical damage, embarrassment, and social and occupational restrictions. Chronic skin diseases may cause financial constraints with repeated sick leave. Some skin conditions can be life-threatening.

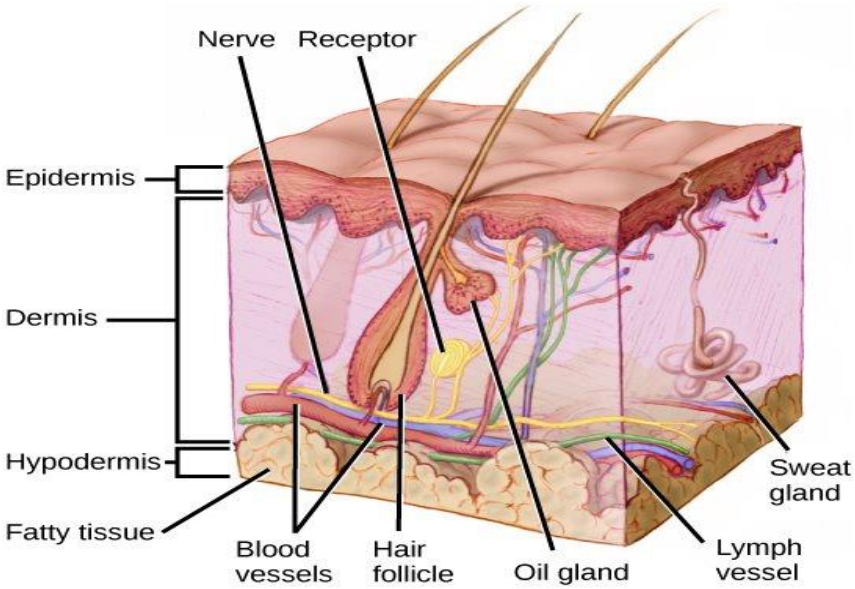
SKIN ANATOMY

The skin is the largest organ of the body, with a total area of about 20 square feet. The skin protects us from microbes and the elements, helps regulate body temperature and permits the sensations of touch, heat and cold.

Skin has three layers:

- The epidermis, the outer most layer of skin, provides a waterproof barrier and creates our skin tone.
- The dermis, beneath the epidermis, contains tough connective tissue, hair follicles, and sweat glands.
- The deeper subcutaneous tissue (hypodermis) is made of fat and connective tissue.

Epidermis develop from the ectoderm and dermis from the mesoderm. The general ectoderm of the early human embryo consists of single layer of cuboidal cells. By fifth week of intra-uterine life, this become double layered. The most superficial layer of flattened cells is called Periderm or epitrichium because the hair later grow from the deeper layer



3.2.1. Structure of the Skin

About the fifth week of fetal development the epidermis and its appendages are developed from the ectoderm. End of second month of intra-uterine life - the derma consists of closely-packed, spindle-shaped mesenchymal cells.

During third month of foetal life –three layers of cells are recognizable, the periderm, the intermediate and the basal layer which is close to the dermis. Fine reticulum fibres are demonstrable, which later increase in number and thickness, form the collagenous fibres.

The subcutaneous fat is apparent by the end of the third month of intra-uterine life, but it becomes abundant only during the later months of foetal life. The nail starts as an epidermal specialization on the dorsum of the tips of the digits.

During fourth month of foetal life - all the sweat glands and the subcutaneous fat are being to develop. During fifth month of foetal life the basal cells multiply rapidly.

During the sixth month of the foetal life -The elastic fibres appear. Most of the sebaceous glands in the body develop in connection with hair

EPIDERMIS

The epidermis is the outer layer of skin. The top layer of epidermis composed of dead cells containing keratin, the horny protein that makes up hair and nail.The epidermis has no blood supply and is nourished almost exclusively by diffused

oxygen from the surrounding air. The thickness of the epidermis varies in different types of skin. It is the thinnest on the eyelids and thickest in palm and sole.

It has 95% keratinocytes which produces a tough protein called keratin but also contains melanocytes, Langerhans cells, Merkel cells and inflammatory cells. Rete ridges are epidermal thickenings that extend downward between dermal papillae. Blood capillaries are found beneath the epidermis and are linked to an arteriole and a venule.

The skin's colour is created by special cells called melanocytes, which produce the pigment melanin. Melanocytes are located in the epidermis.

Layers

The epidermis is composed of 5 layers depending on the region of skin being considered. Those layers in descending order are,

1. **Stratum corneum / Horny layer**
   - ✓ The most superficial layer of the epidermis from which dead skin sheds and is the thickest of epidermal layers having 15 – 30 layerrs of keratinized cells.
   - ✓ The Stratum corneum is also normally devoid of nuclelic and consists of eosinophilic layers of keratin.
   - ✓ Most of the barrier functions of the epidermis localize to this layer.
2. **Stratum lucidum**
   - ✓ It is a clear or translucent layer.
   - ✓ It is present only in palms and soles.
   - ✓ It is composed of flattened and hardened skin cells madeof keratin.
3. **Stratum granulosum (Granular layer)**
   - ✓ The stratum granulosm is one to four cellular layers thick consistitng of flattened rows of cells
   - ✓ This layer produces large amount of the protein keratin.
   - ✓ Keratin is extremely durable and water resistant.It is also the protein that forms the basic structure of hair and nails.
4. **Stratum spinosum / Spinous layer/ Pricky cell layer**

This layer is composed of several layers of polygonal prickle cells (or) squamous cells. The layers become flat as they are near the surface, so that their long

axis appears parallel to the skin surface. These cells possess intercellular bridges (or) Tonofilaments.

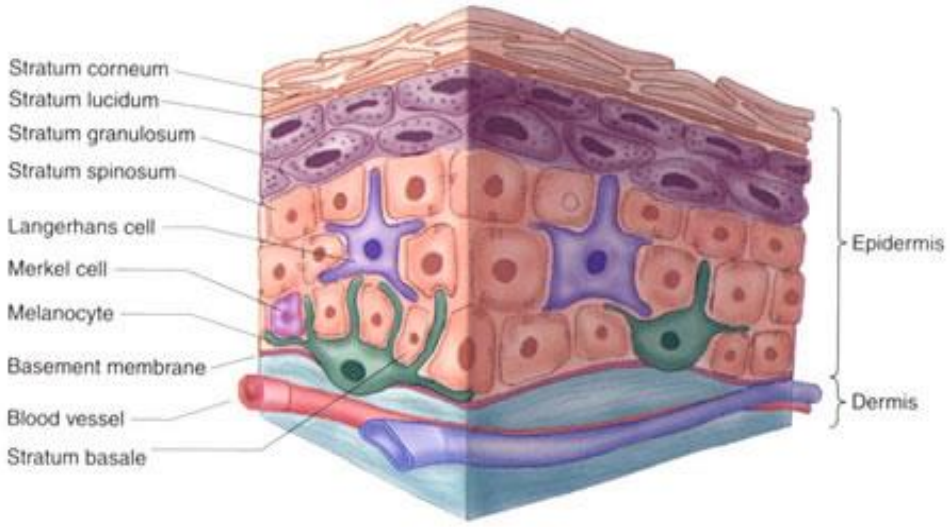
5. Stratum Basal/germinal layer

Composed mainly of proliferating and non-proliferating keratinocytes, attached to the basement membrane by hemidesmosomes.

Melanocytes are present, connected to numerous keratinocytes in this and other strata through dendrites.

Merkel cells are also found in the stratum basale with large numbers in touch-sensitive sites such as the fingertips and lips. They are closely associated with cutaneous nerves and seem to be involved in light touch sensation.[9]

The epidermis is separated from the dermis, its underlying tissue, by a basement membrane.

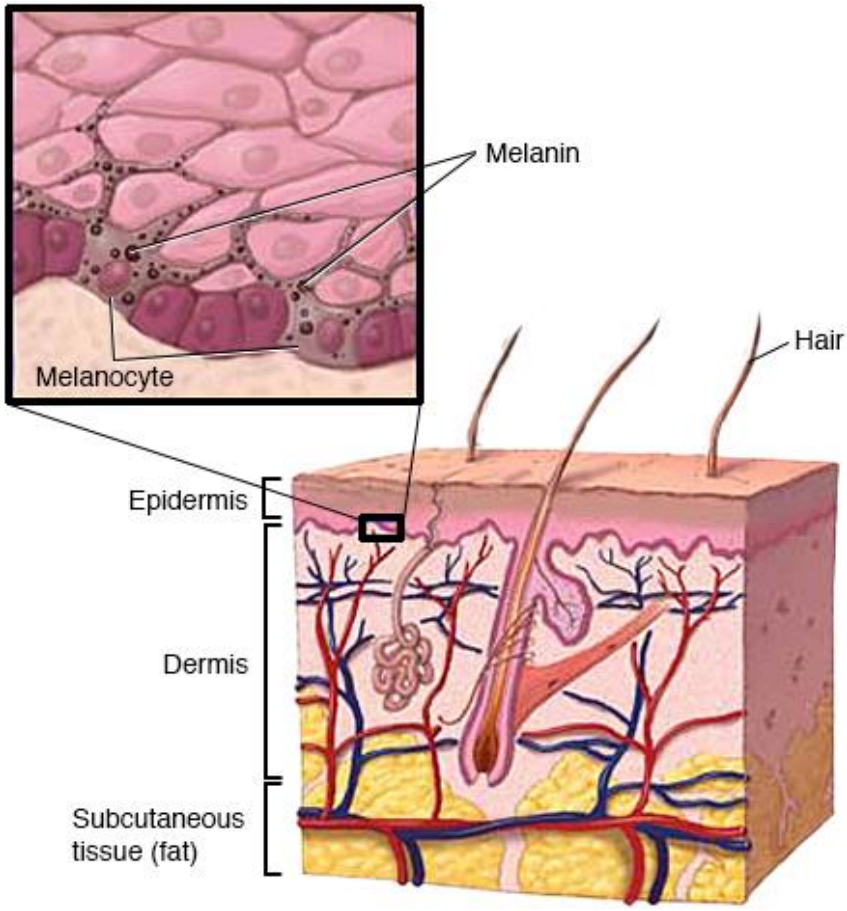


Layers of the skin

Melanocytes

They are melanin producing neural crest derived cells located in the bottom layer of the skin's epidermis, the middle layer of the eye , the inner ear, meninges, bones and heart. It is formed from tyrosine by oxidation metabolism and polymarization.

They are spidery black cells that produce the brown to black pigment known as melanin.Melanin is the pigment primarily responsible for skin colour. Once synthesised, melanin is contained in a special organelle called a melanosome and moved along arm-like structures called dendrites, so as to reach the keratinocytes.



Melanocytes

DERMIS

The **dermis** is a thick layer of skin between the epidermis and subcutaneous tissues, that primarily consists of dense irregular connective tissue and cushions the body from stress and strain. The dermis also varies in thickness depending on the location of the skin. The dermis is a tough layer of skin.

The dermis is tightly connected to the epidermis through a basement membrane. Structural components of the dermis

Collagen

Elastic fibers

Extrafibrillar matrix.

The hair follicles, sweat glands, sebaceous glands, apocrine glands, lymphatic vessels and blood vessels are present in the dermis.

The dermis is composed of three major types of cells

Fibroblasts

Macrophages

Adipocytes

Dermis is divided into two layers, the superficial area adjacent to the epidermis called the papillary region and a deep thicker area known as the reticular dermis.

Papillary dermis (stratum papillarosum)

The papillary dermis is the uppermost layer of the dermis. It accounts for 1/5 th of the dermis. It intertwines with the rete ridges of the epidermis and is composed of fine and loosely arranged collagen fibers.

The papillary region is composed of loose areolar connective tissue. This is named for its finger like projections called papillae, that extend toward the epidermis and contain either terminal networks of blood capillaries or tactile Meissner's corpuscles

The papillary layer provides the layer above it, the epidermis, with nutrients to produce skin cells called keratinocytes. It also helps regulate the temperature of our skin and thus the body as a whole.

Reticular dermis (stratum reticularosum)

The **reticular dermis** is the lower layer of the dermis, found under the papillary dermis, composed of dense irregular connective tissue featuring densely packed collagen fibers.

The reticular layer serves to strengthen the skin and also provides our skin with elasticity.

The reticular region is usually much thicker than the overlying papillary dermis. It receives its name from the dense concentration of collagenous, elastic, and reticular fibers that weave throughout it.

The reticular layer also contains hair follicles, sweat glands, and sebaceous glands.

The sweat gland can either be apocrine, such as those found in the armpits and the groin area, or the eccrine glands, which are found all over the body. The former help contribute to body odor and the latter help regulate our body temperature through the process of evaporation.

The sebaceous glands found in the dermis secrete a substance called sebum that helps to lubricate and protect our skin from drying out.

HAIR

The hair grows from the bottom of the follicle. It has, therefore, an intracutaneous portion present in the hair follicle and the shaft. The hair follicle consists of epithelial and connective tissue components. Hair is composed primarily of keratin. The dead keratinocytes fuse together to form the hair.

ARRECTORES PILORUM

These are small bundles of smooth muscle attached to each hair follicle that contracts in response to cold, fright and other emotions. When the muscle contracts, the hair becomes more erect, the follicle is dragged upwards so as to become prominent on the surface of the skin producing what is known as 'goose skin'.

NAILS

The nails are thickening of the deeper part of the stratum corneum that develops as specially modified portion of the skin called nail bed. The nails is composed of clear horny cells, resembling stratum lucidum but are much more keratinized.

The dermis also contains:

- Nerve endings that transmit various stimuli such as pain, itch, pressure, and temperature. Specialized Nerve Cells
    - ✓ Pacinian corpuscles –pressure receptor
    - ✓ Meissner corpuscles– touch receptor
    - ✓ Ruffini corpuscles– hot receptor
    - ✓ End bulbs of Krause –cold receptor
    - ✓ Free nerve ending– pain receptor
- Lymphatic vessels that transport immune system cells, the cells that help destroy infectious organisms that may have found their way into our body via a scratch on the skin.
- Collagen, a protein that helps strengthen our skin, and elastin, a protein that helps keep our skin flexible.

- The dermis is well supplied with blood vessels, both arterioles and capilleries that originate from arteries and veins in the subcutaneous layer. Blood vessels within the dermis supply nutrients to the stratum basale as well as to the cellular structures of the dermis such as glands and hair follicles. Those blood vessels provide nourishment and waste removal for both dermal and epidermal cells.

HYPODERMIS / SUBCUTANEA

- ✓ Beneath the dermis is the deepest layer of our skin.
- ✓ It contains many collagen cells as well as fat. Fat, in particular, helps insulate our body from the cold and act as a cushion for our internal structures.

PHYSIOLOGY

FUNCTIONS OF THE SKIN:

1. PROTECTIVE FUNCTION

It protects underlying tissues and organs from chemicals, microbes and shock impacts. The cornified layer of the epidermis possess properties of physical toughness, strength, flexibility, elasticity and also retards proliferation of microorganism and their penetration. The skin protects the body from from ultra violet damage from the sun by producing melanin.

2. THERMOREGULATION

The skin contains several types of receptors which are involved in thermoregulation. Skin regulates body temperature by constricting blood vessels and driving blood inward in cold temperatures to preserve body heat and produce sweat in warm temperatures to cool the body by water evaporation.

3. SENSE ORGAN

Sensation is a very important function of the skin. Skin preserves a number of sensations like touch, pressure, warmth, cold and pain

4. STORAGE FUNCTION

The skin acts as two way barrier to prevent the inward or outward passage of water and electrolyte. The dermis and subcutaneous fatty tissue acts as storage organ of energy and others. It synthesize and stores vitamin D.

5. ABSORPTION

The skin surface also performs absorptive function and is the basis of topical therapy in dermatology. The skin is capable of absorbing fat soluble nutrients such as vitamins A, D, E and K.

6. EXCRETION

Some of the toxins may be excreted through the skin.

7. IMMUNE SURVEILLANCE

This immunological function is performed by langerhans' cells, dendritic cell, and keratinocytes. Thus the skin forms the front line defense of the body against invasion by foreign agents.

8. MECHANICAL FUNCTION

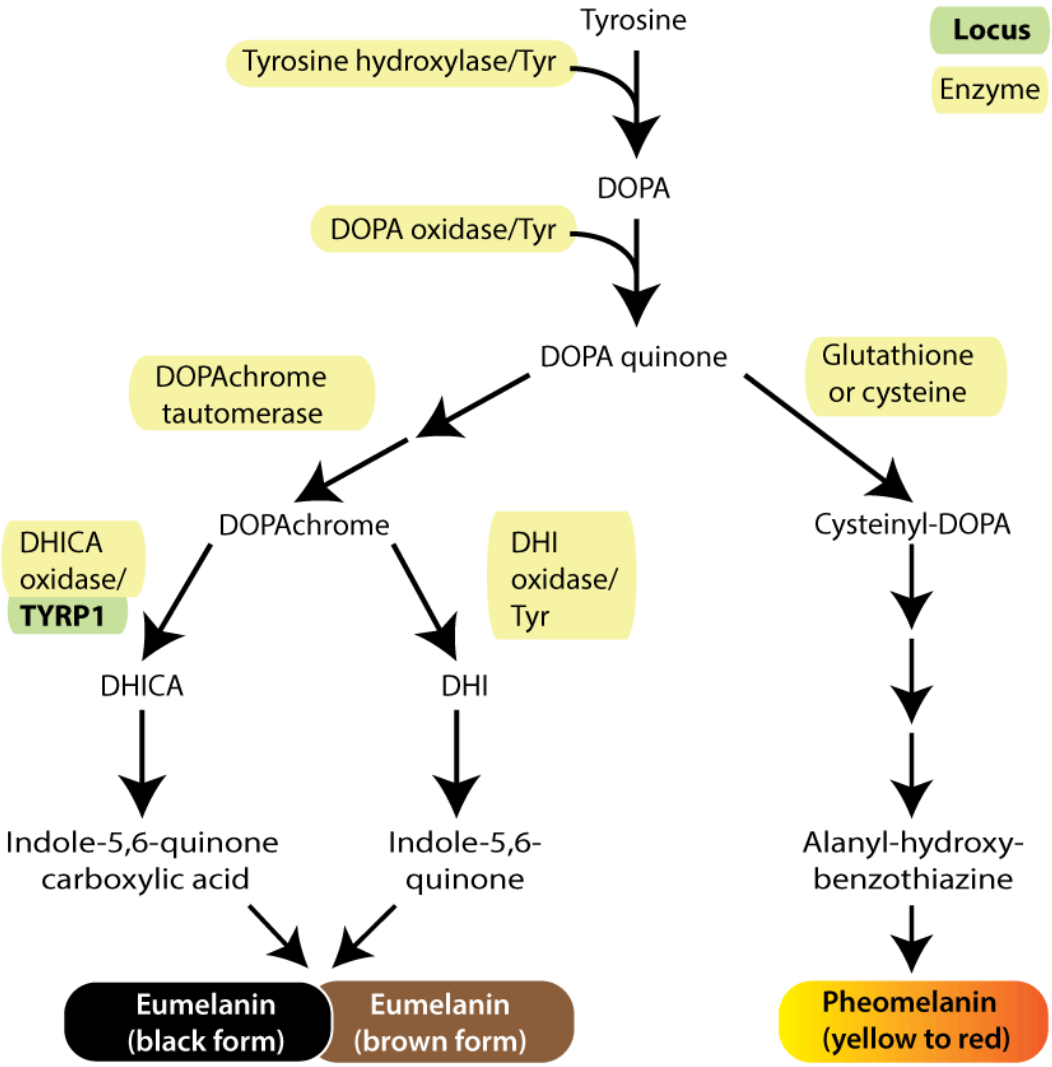
The mechanical properties of the skin depend mainly on the dermis, although, the epidermis and subcutaneous fats also plays some role.

9. COSMETIC FUNCTION

Colour of the skin, hair and nail are important for their decorative value. Hair does not perform a vital physiological function but it does provide a sexually attractive ornament.

Melanin Formation

Melanin synthesis is initially catalysed by a copper containing enzyme known as tyrosinase. The broad of melanin synthesis from the oxidation of phenylalanine or tyrosine are as follows.



Melanin Formation

Melanin produced in the melanocytes is donated via their dendrites to neighbouring keratinocytes. Melanin formation in both human and amphibian skin is augmented by the hormone known as intermedin or melanocyte – stimulating hormone (MSH) secreted by the pars intermedia of the pituitary gland.

Adrenocortico tropic hormone (ACTH) secreted by Anterior Pituitary has melanocyte – stimulating activity similar to MSH although to a much lower degree.

MSH causes the serum copper to rise and this is accompanied by inner case in the melanin formation.

Diminished formation of melanin is seen in albinism and leucoderma. In melanotic sarcoma, melanin may be found in the urine.

VITILIGO

White skin is the literal meaning of leucoderma, derma being derived from the Greek words, leucas and dermis. Leucas means white and dermis means skin.

Vitiligo is a non contagious acquired pigmentation disorder characterized by sharply defined white patches of variable shape and dimensions, increasing in size and number with time.

The disorder affects all races and both sexes equally, however, it is more noticeable in people with dark skin

DEFINITION

Vitiligo is defined as acquired idiopathic , circumscribed, progressive hypopigmentation of skin and hair. A type of leucoderma often familial characterized microscopically by an absence of melanocytes.

This disease is characterized by the presence of white macules or patches on the skin caused by the loss of functioning epidermal melanocytes Vitiligo can also affect the mucous membranes and the eye.

It can be examined by naked eye and can furnish a lot of information about the person and the disease.

EPIDEMIOLOGY

Vitiligo is an hypopigmentation disorder that affects approximately 1-2 % of the population worldwide.

In India 0.25-2.5% were affected. 30% hereditary condition.

Stable type of vitiligo was common which accounted for 65.21%. Lower lip was involved in 75% of mucosal vitiligo.

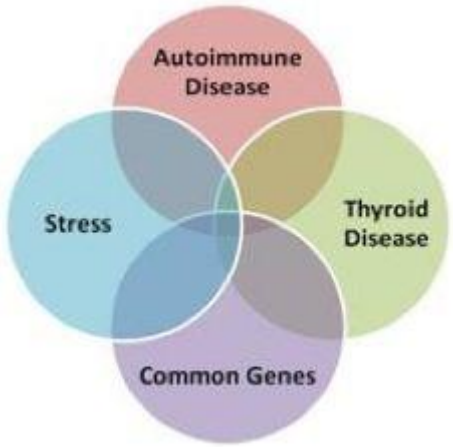
Lower limbs were the most common site of onset of vitiligo. Family history exists in 6.25%-38% of patients with vitiligo

HISTOPATHOLOGIC CHANGES IN VITILIGO

- ✓ Absence of melanocytes
- ✓ Negative silver stain for melanin
- ✓ Negative dopa reaction
- ✓ Lymphocytic inflammation may be seen
- ✓ Melanophages may be seen.

- ✓ In the affected area the basal cells and the keratinzing cells of the other layers of epidermis do not contain melanin pigment granules in them.
- ✓ At the border of the patches of vitiligo the melanocytes often appear large and posses long dendritic process filled with melanin granules.
- ✓ Electron microscopic studies confirm the absence of melanocytes in areas of long standing vitiligo.
- ✓ There are collections of mononuclear cells at dermo epidermal junction at the border between vitilliginous and normal skin. These cells are predominately small lymphocytes. In the long standing cases where the skin has become thick and scaly, varying amount of keratosis is seen.

PATHOPHYSIOLOGY:



Pathogenesis of Vitiligo

Vitiligo is a cutaneous pigmentary disorder caused by selective destruction of melanocytes and is characterized by progressive, patchy loss of pigmentation from skin.Vitiligo has been proposed to be a multifactorial disease with genetic susceptibility and environmental factors both thought to play a role.

The TYR gene encodes the protein tyrosinase, which is not a component of the immune system, but is an enzyme of the melanocyte that catalyzes melanin biosynthesis, and a major autoantigen in generalized vitiligo.

Although several theories have been proposed about the pathogenesis of vitiligo, there are a few major hypothesis for the pathogenesis of vitiligo which include the genetic, neural, autoimmune, Oxidant-antioxidant mechanisms and melanocytorrhagy theories.

Autoimmune and cytotoxic hypotheses

Aberration of immune surveillance results in melanocyte dysfunction or destruction. Autoimmune diseases such as thyroid diseases and diabetes mellitus are often associated with vitiligo. These diseases cause defects in the immune system, which can cause destruction of melanocytes and the loss of pigmentation . The autoimmune theory proposes alteration in humoral and cellular immunity in the destruction of melanocytes of vitiligo.

In addition, antibodies against melanocytes were found in serum of patient, and these can engage the apoptosis of melanocytes when they are present . T cells were also found in perilesional vitiligo plaque biopsies and they are enriched with cytotoxicity against melanocyte antigens. Destruction of melanocytes may be directly mediated by autoreactive CD8+ T cells. Activated CD8+ T cells have been demonstrated in perilesional vitiligo skin.

Vitiligo is sometimes associated with autoimmune and inflammatory diseases such as Hashimoto's thyroiditis, scleroderma, rheumatoid arthritis, type 1 diabetes mellitus, psoriasis, Addison's disease, pernicious anemia, alopecia areata, systemic lupus erythematosus, and celiac disease.

Neural hypothesis

A neurochemical mediator destroys melanocytes or inhibits melanin production. The neural hypothesis is based on the contact of the melanocytes with nerve endings in depigmented skin . Neuropeptides and nerve growth factors such as tumor necrosis factor-α, intercellular adhesion molecule-1 and interferon-γ were found in perilesional skin, which suggest that nerves can have a role in destruction of melanocytes . The toxic hypothesis suggests that the mechanism of natural protection of melanocytes is defective. The melanocytes are unable to eliminate toxic molecules, and these are accumulated in the cells

Oxidant-antioxidant mechanisms

An intermediate or metabolic product of melanin synthesis causes melanocyte destruction. Studies suggest that accumulation of free radicals toxic to melanocytes leads to their destruction. Because patients with Vitiligo exhibit a characteristic

yellow/green or bluish fluorescence in clinically affected skin, this led to the discovery that the fluorescence is due to accumulation of 2 different oxidized pteridines. The overproduction of pteridines led to the discovery of a metabolic defect in tetrahydrobiopterin homeostasis in patients with Vitiligo, which results in the accumulation of melanocytotoxic hydrogen peroxide.

Melanocytorrhagy hypothesis

It emphasizes that depigmentation is because of chronic detachment of melanocytes. Trauma or repeated friction can contribute toward the detatchment of melanocytes over time. Melanocytes in unstable vitiligo have been found to lose the ability to adhere to key surrounding structures. Tenascin, an extracellular matrix molecule that inhibits adhesion of melanocytes to fibronectin, has been detected in the basal membrane in the papillary dermis and can contribute toward chronic detatchment and epidermal loss of melanocytes.

Genetics of vitiligo

The inheritance of vitiligo may involve genes associated with the biosynthesis of melanin, a response to oxidative stress, and regulation of autoimmunity. Human leukocyte antigens (HLAs) may be associated, but not in a consistent manner.

For example, HLA-DR4 is increased in blacks, HLA-B13 is increased in Moroccan Jews, and HLA-B35 is increased in Yemenite Jews. An association with HLAB13 is described in the presence of antithyroid antibodies. Only one gene, SMOC2, is in the region of association, within which SNP rs13208776 attained genome-wide significance for association with other autoimmune diseases and vitiligo Other Common factors are,

- ✓ Nutritional - defects in copper, proteins and vitamins in diet, digestive upsets like amoebiasis, helminthics, chronic diarrhoea, dysentery etc.,
- ✓ Endocrines – Association with thyrotoxicosis and diabetes.
- ✓ Trophoneurosis and autonomic imbalance – emotional stress and strain.
- ✓ Infections and toxic products, Enteric fever ill health, focal sepsis.
- ✓ Drugs and chemicals
- ✓ Triggers also include inflammatory skin conditions, burns, intralesional steroid injections and abrasions.

Clinical features

White patches on the skin are the main sign of vitiligo. These patches are more common in areas where the skin is exposed to the sun.

The patches may be on the hands, feet, arms, face, and lips. Other common areas for white patches are:

The armpits and groin (where the leg meets the body), around the mouth, eyes, nostrils, navel, genitals, rectal areas, Loss of colour in the tissues that line the inside of your mouth and nose (mucous membranes), Loss of or change in colour of the inner layer of the eyeball (retina)

People with vitiligo often have hair that turns gray early. Those with dark skin may notice a loss of colour inside their mouths.

Initially, the vitiligo starts as a simple spot, a little paler than the rest of the skin. But gradually, as time passes, this spot will become much paler until it becomes white.

The shape of these patches are completely irregular, and, at times, the edges can become a little inflamed with a slight red tone, sometimes resulting in itchiness.

Other than the appearance of the spots and occasional itchiness, vitiligo does not cause any discomfort, irritation, soreness or dryness in the skin.

Predicting whether vitiligo will spread, and by how much, is particularly difficult. The spread of white patches might occur in a matter of weeks for some, and for others, they might stabilize, not growing for months or even years.

If the first symptoms of the white patches are symmetrical (non-segmental vitiligo), the development is much slower than if the patches are in only one area of the body (segmental vitiligo).

Depending on the type of vitiligo, the discolored patches may cover:

Many parts of the body

With this most common type, called generalized vitiligo, the discolored patches often progress similarly on corresponding body parts (symmetrically).

Only one side or part of the body

This type, called segmental vitiligo, tends to occur at a younger age, progress for a year or two, then stop.

One or only a few areas of the body

This type is called localized (focal) vitiligo. Sometimes the patches stop forming without treatment. In most cases, pigment loss spreads and eventually involves most of your skin. Rarely, the skin gets its color back.

Types of vitiligo

Scientists separate vitiligo into two types

- Non-segmental vitiligo
- Segmental vitiligo.

Non-segmental vitiligo

Non-segmental vitiligo is the most common type of vitiligo and occurs in up to 90% of people who have the disorder. In non-segmental vitiligo, the patches often appear equally on both sides of the body, with some measure of symmetry.

New patches also appear over time and can be generalized over large portions of the body or localized to a particular area.

NSV can come about at any age .The symmetrical patches most commonly appear on skin that is exposed daily to the sun, such as the face, neck and hands, but can also appear in other areas:

- Backs of the hands
- Arms
- Eyes
- Knees
- Elbows
- Feet
- Mouth.

Non-segmental vitiligo is further broken down into sub-categories:

Generalized vitiligo

No specific area or size of patches, this is the most common type

Acrofacial vitiligo

Mostly on the fingers or toes

Mucosal vitiligo

Depigmentation generally appears around the mucous membranes and lips

Universal vitiligo

Depigmentation covers most of the body, this is very rare

Focal vitiligo

One or few, scattered white patches in a discrete area. Most often occurs in young children.

Segmental vitiligo

Segmental vitiligo has a different form; this condition spreads more rapidly but is considered more constant and stable than non-segmental. It is much less common and affects only about 10% of people with vitiligo.

Segmental vitiligo is more noticeable in early age groups, affecting about 30% of children diagnosed with vitiligo.

It is non-symmetrical and usually tends to affect areas of skin attached to nerves arising in the dorsal roots of the spine. It is more stable, less erratic and responds well to topical treatments.

Complications

People with vitiligo may be at increased risk of:

- Social or psychological distress
- Sunburn and skin cancer
- Eye problems, such as inflammation of the iris (iritis)
- Hearing loss

PATIENT EVALUATION

Assessment of severity — The evaluation of the patient with vitiligo involves a detailed history and a complete skin examination to assess disease severity and individual prognostic factors. Factors that may influence the approach to treatment include:

- Age at onset of lesions
- Type of vitiligo (segmental, nonsegmental)
- Mucosal involvement, Koebner phenomenon

- Rate of progression or spread of lesions
- Previous episodes of repigmentation
- Type and response to previous treatments
- Family history of vitiligo and/or autoimmune diseases
- Presence of concomitant diseases
- Current medications and supplements
- Occupation, exposure to chemicals
- Effects of disease on the quality of life

A full-body skin examination should be performed to assess the extent of the disease, with particular attention to sites of vitiligo predilection, such as the lips and perioral area, periocular areas, dorsal surface of the hands, fingers, flexor surface of the wrists, elbows, axillae, nipples, umbilicus, sacrum, groin, inguinal / anogenital regions, and knees.

The percentage of the body area involved can be estimated by the so-called 1 percent rule or "palm method." In both children and adults, the palm of the hand, including the fingers, is approximately 1 percent of the total body surface area (TBSA), while the palm excluding the fingers is approximately 0.5 percent of the TBSA. An alternative method is the "rule of nines":

- Each leg represents 18 percent of the TBSA.
- Each arm represents 9 percent of the TBSA.
- The anterior and posterior trunk each represent 18 percent of the TBSA.
- The head represents 9 percent of the TBSA.

Goals of treatment

The goals of treatment for vitiligo should be set with the individual patient or parents in the case of children, based upon the patient's age and skin type, the extent, location, and degree of disease activity, and the impact of the disease on the patient's quality of life. An open discussion with the patient about the limitations of treatment may be helpful to create realistic expectations.

Psychosocial aspects

The patient's psychologic profile and ability to cope with a lifelong disease should be carefully evaluated at the time of treatment planning. Psychologic support should be offered to patients if needed

The main symptom of vitiligo is the appearance of lesions, with an often distressing sense of disfigurement and associated stigma.

Social isolation, reduced sense of worth, adverse effects on education, occupation, and personal relationships and depressive illness can be consequences

Inferiority complex immediately following the start of disease, the patient thinks himself inferior to those with whom he was at par or excelled for so long.

When the patient feels his disease is incurable he becomes gradually depressed.

Diagnosis:

1. The distribution, the age of onset and the hyper pigmented border will suggest the diagnosis.

2. Vitiligo areas are milky white while other lack this milky white colouration.

3. It is usually apparent. In doubtful and early case, Wood's lamp is great help in diagnosis.

4. Careful examination of the texture of the unpigmented skin should exclue lichen sclerosus and scleroderma.

5. Post-inflammatory leucoderma, which is frequent in the darker races, shows an irregular mottling of hyper pigmented and hypopigmented blotches.

6. Stationary patches are well-defined and have hyperpigmented borders.

7. Sensations are normal, so is texture unless the patches have been irritated with treatment.

8. Absence of scaling, crusting and itching help to eliminate seborrhoeids and pityriasis versicolor.

9. These areas often fluorescence a golden yellow when examined under a Wood's lamp. The hypomelanotic macules in leprosy are anaesthetic.

10. Examination of the skin in long wave UVR helps distinguish whether there is total depigmenation (as in Vitiligo) or not. It may also detect areas of depigmenation not easily seen in ordinary daylight, as well as detecting a lemon-yellow fluorescence seen in some cases of pityriasis versicolor.

Differential Diagnoses

Pityriasis alba

It appears as white patches on the upper arms and sometimes the thighs. Close examination shows an indistinct border and fine surface scale.

Tinea versicolor

It is casused by yeast. It affects the chest and back. Patches have a fine scale on the surface. The colour of the patches varies from pale to orange brown.

Halo nevi

It develop a white border. One or several of these nevi may be present on the back of children.

Leprosy

One or several paler macules on trunk or limbs that are hypoaesthetic.

White macules of affecting tuberous sclerosis

Uncomming development of anomaly of CNS, connective tissue and skin; several "maple leaf" shaped hypopigmented macules.

Post inflammatory hypopigmentation

After inflammatory skin disease (after eczema or trauma to the skin; irregular in shape and in depth of pallor).

Chemical toxicity

May look very much like vitiligo; seen in workers in rubber industry exposed to parateriary benzyltoluence.

Outlook (Prognosis)

The course of vitiligo varies and is unpredictable. Some areas may regain normal pigment , but other new areas of pigment loss may appear. Skin that is repigmented may be slightly lighter or darker than the surrounding skin. Pigment loss may get worse over time.

Treatment

- ✓ Vitiligo is difficult to treat. Early treatment options include the following:
- ✓ Phototherapy, a medical procedure in which your skin is carefully exposed to ultraviolet light. Phototherapy may be given alone, or after you take a drug that makes your skin sensitive to light.
- ✓ Certain lasers may help the skin repigment.

- ✓ Medicines applied to the skin, such as corticosteroid creams or ointments, immunosuppressant creams or ointments such as pimecrolimus (Elidel) and tacrolimus (Protopic), or topical drugs such as methoxsalen (Oxsoralen) may also help.
- ✓ Skin may be moved (grafted) from normally pigmented areas and placed onto areas where there is pigment loss.
- ✓ Several cover-up makeups or skin dyes can mask vitiligo.
- ✓ In extreme cases when most of the body is affected, the remaining skin that still has pigment may be depigmented. This is a permanent change that is used as a last option.
- ✓ It is important to remember that skin without pigment is at greater risk for sun damage. Be sure to apply a broad-spectrum (UVA and UVB), high-SPF sunscreen or sunblock.
- ✓ Sunscreen can also be helpful for making the condition less noticeable, because unaffected skin may not darken in the sun.
- ✓ Use other safeguards against sun exposure, such as wearing a hat with a broad rim and long sleeve shirt and pants.
- ✓ Surgical therapies — Surgical therapies have been used for vitiligo for the past 25 years and remain viable options for patients with localized depigmented areas that have been unresponsive to medical intervention.

They include:

- Autologous suction blister grafts
- Minigrafts or punch grafts
- Split-thickness grafts
- Autologous melanocyte cultures
- Cultured epidermal suspensions
- Autologous noncultured epidermal cell suspension
- Hair follicle transplantation

DIET AND RESTRICTIONS

- Occupation
- Cosmetic things
- Diet

- During bathing – the powder of Bengal gram and green gram or any other herbal products can be used.
- Vinegar, cooking soda, food enriched with alcohol must be avoided. These items may promote bleaching of skin pigment.
- Using soaps and detergents also promote bleaching of skin.
- Copper and zinc content vegetable such as cooked green gram or Bengal gram at least one time a day.
- Highly nutritious food like spinach, pomegranate, cheese, butter, milk, almond, germinating grams and foods rich in tyrosinase to be added.

DRUG REVIEW

INTERNAL MEDICINE: RASA CHENDHURAM

INGREDIENTS:

Rasam (Hydragyram)

Gandhagam (Sulphur)

Aridharam (Arsenic trisulphide)

Egg shell

RASAM (HYDRAGYRUM)

Rasam comes under the classification of pancha sootham. It is one of the important siddha raw drugs .

இரசத்தின் பொதுக்குணம்

விழிநோய் கிரந்தி குன்மம் மெய்ச்சூலை புண்குட்
டழிகாலில் விந்துவினால் அத்தை - வழியாய்
புரியு விதி யாது புரியினோ யெல்லாம்
இரியுவிதி யாது மில்லை

Uses	**:**	It cures venereal diseases , skin diseases , eight types of ulcers.
Taste	:	six tastes present, sweet is dominant.
Potency	:	hot and cool
Action	**:**	alterative, antiseptic, purgative, diuretic, tonic

GENERAL PROPERTIES :

Atomic number	:	80
Phase	:	liquid
Melting point	:	234.3210
Heat of fusion	:	2.29 kj /mol
Heat of vaporization	:	59.11 kj / mol

GANDHAGAM (SULPHUR)

Gandhagam comes under the division of paadanangal. It is one of the most useful raw drug in siddha.

நெல்லிக்காய்க் கந்தகத்தின் பொதுகுணம்

(GOOSEBERRY SULPHUR)

“நெல்லிக்காய்க் கந்திக்கு நீள்பதினெண் குட்டமந்தம்
வல்லை கவிசைகுன்ம வாயுகண்ணோய் - பொல்லா
விடக்கடிவன் மேகநோய் வீறுசுரம் பேதி
திடக்கிரசு ணீகபம்போனந் தேர்.”

Uses: It cures eighteen types of skin diseases, leprosy, veneral diseases, ulcer, etc,.

Taste: kaippu, thuvarppu

Action : astringent, laxative, alterative, insecticide

General properties :

Atomic number	:	16
Phase	:	solid
Melting point	:	388.36 k
Heat of fusion	:	1.727 kj /mol
Heat of vaporization	:	45 kj / mol

THALAGAM (YELLOW ARSENIC TRISULPHIDE)

Thalagam is come under the division of padanangal. It is one of the important raw drug in siddha system.

தாளகம் பொதுக்குணம்

“தாளகத்தின் பேருரைக்கத் தாலுகவுள் நோய்குஷ்டம்
நீளக் குளிர்காய்ச்சல் நீடுகபம் - நாளகங்கொள்
துஷ்டப் பரங்கிப்புண் சூழழுகண் மண்டைநோய்
கிட்டப் படுபமா கிளத்து.”

uses: it is effective in treatment of skin diseases, urinary tract infections, incurable ulcers, etc.

Action : antipyretic , expectorant , emetic , convalescent , tonic.

EXTERNAL MEDICINE: PALAGARAI KUZHAMBU

INGREDIENTS:

Palagarai (Marine shell)

Lemon juice

Gingelly oil

PALAGARAI (CYPREA MONETA)

Palagarai is considered as one of the five wealth of the sea. The white marine shell is considered as superior for medicinal purposes

PALAGARAI

பலகறை பொதுக்குணம்

மந்தந்தா கங்கிரகணி மாவிடச் சுரங்கண்ணோய்
தொந்தம் பரிநாமச் சூலைகய - மிந்த
வுலகறையைக் காலொடிவை யோடு நரைத்த
பலகறையை காணினியம் பார்.

Uses: it cures skin diseases, jaundice, liver enlargement, spleen enlargement, eye diseases etc.

suvai: kaippu

action: rubifacient, Stimulant, Expectorant, Demulcent.

LEMON

Botanical name *: citrus limon*

Family : rutaceae

எலுமிச்சை பொதுக்குணம்

தீதெலு மிச்சங்காய் டேர்முத்தோ டத்தையுமுள்
வாதகப சூலையையும் மாகொடிய - சாதியெனுஞ்
சர்த்திகுன் மத்தையுமுள் தங்கமருந் திட்டதையும்
பித்தவெப்பை யுந்தணிக்கும் பேசு.

suvai: pulippu

action: anti bacterial , anti fungal , antimicrobial, anti oxidant

GINGELLY OIL

Botanical name*:* *Sesamamum indicum*

Family: meliaceae

Parts used: seed

நல்லெண்ணெயின் பொதுக்குணம்

“புத்திநயனக்குளிர்ச்சி பூரிப்பு மெய்ப்புளகஞ்
சத்துவங் கந்தி தனியிளமை - மெத்தவுண்டாங்
கண்ணோய் செவிநோய் கபாலவழல் காசநோய்
புண்ணோய் போ மெண்ணெய்யாற் போற்று. “

Uses: oil used for cooling effect , external application for wounds and scabies.

Suvai : inippu

Actions : Antifungal, Anticancer, Anti Aging, Anti coagulant, Anti Inflammatory

MATERIALS AND METHODS:

SELECTION OF THE TRIAL MEDICINES:

I have selected the trial drug " **Rasa Chendhuram" (Int)** for this study from Classical Siddha literature **Pulipanni Vaithiyam -500** and "**palagarai kuzhambu" (Ext)** from **Gunapadam-thaadhu seevavaguppu.**

SOURCE OF RAW DRUGS:

The required raw drugs are produced from as well reputed indigenous drug shop. The raw drugs will be authenticated by the concerned pharmacognosist, Government siddha medical college, ,arumbakkam, Chennai. As i have registered my trial in clinical registry of India (CTRI). My CTRI no is (CTRI/2017/07/008969) .

STANDARD OPERATING PROCEDURE:

MEDICINE – 1

RASA CHENDHURAM

INGREDIENTS:

Rasam (Hydragyram)	-	35 gm
Gandhagam (Sulphur)	-	35 gm
Aridharam (Arsenic trisulphide)	-	35 gm
Egg shell	-	Q.S

METHOD OF PURIFICATION:

PURIFICATION OF RASAM (MERCURY):

Materials used :

Mercury , brick powder , turmeric powder , acalypha indica leaf juice.

Equipments used:

Stove, mudplate.

Procedure:

Trituration

Mercury after purification

Mercury purification

Mercury was tritured with brick powder and turmeric powder and washed with water. Then the mercury was boiled with acalypha juice for about 30 minutes .

PURIFICATION OF GANDHAGAM (SULPHUR):

Materials used :

Gandhagam , milk

Equipments used:

Iron spoon, mud pot , stove , tissue paper.

Procedure :

Melting sulphur

Sulphur poured into milk

Sulphur after purification

Gandhagam is placed in an iron spoon , the spoon is heated till the gandhagam melts. Then it is poured in milk. This is repeated for 2 times . After that gandhagam is taken out and washed with cool water and allowed it to dry.

PURIFICATION OF ARSENIC TRISULPHIDIUM (THALAGAM) :

Materials used :

Thaalagam , limestone , small cloth

Equipments used:

Stove , mud pot , small cloth .

Procedure :

Thalagam buried into limestone

Thalagam after purification

Thalagam is placed in small cloth and tied with a small rope. Then it was buried in limestone . water was poured till the limestone immersed and it is heated till water evaporated completely . the thalagam is taken out and washed in cool water and allowed it dry.

METHOD OF PREPARATION:

Heating

Trituration

Final product
(Rasa chendhuram)

The above mentioned purified raw drugs is to be added in the stone mortar and made as a fine powder. Then the fine powder is to be fried well. Next the egg shell is powdered. Place the half the quantity of powdered egg shell in a mud plate as a layer. Then spread the powdered raw drug as a second layer then put the remaining quantity of egg shell spreaded on it, then it is heated with kukkuda pudam (10 cow dung cakes) to make as a chendhuram. Then the end product is preserved in an air tight container.

DOSAGE	:	65 mg
ADJUVANT	**:**	Palm jaggery.
INDICATION	**:**	Parangisogai, Kiranthi, Kuttarogam, Thaadhunattam, Lingaputtru, Vippurudhi.

MEDICINE – 2

EXTERNAL MEDICINE

PALAGARAI KUZHAMBU

INGREDIENTS:

- Palagarai (Marine shell)
- Pazhacharu (*Citrus limon*)
- Gingelly oil

METHOD OF PREPARATION:

Palagarai is powdered and kept in mud pot. Lemon juice is added to it, kept for 6 days and allowed to dried. The dried palagarai is mixed well with gingelly oil and applied over the skin.

INDICATIONS: Kuttam, Kurainoi, pungal.

STANDARDIZATION PARAMETERS :

Traditional way of testing Chendhuram :

1. Colour:

Red in colour without any shiny appearance

2. Taste and odour:

Tasteless and odourless

3. Luster

Did not regain luster on heating again at same temperature

4. Floating on water

Sample floats on water. Did not immediately immersed in water

5. Finger furrows test.

Impinged in the papillary ridges when the sample rubbed in between Index finger and thumb

PHYSICO- CHEMICAL ANALYSIS

Determination of pH

1% solution of Rasa Chendhuram was prepared in distilled water and pH was determined by using pH meter Systronics digital pH meter.

Determination of moisture content

Moisture content was determined by LOD (Loss on Drying) method. 3gm VPM was taken and kept in oven at 105^0c till a constant weight was obtained. Amount of moisture present in the sample was calculated as referred to the air dried drug.

Total Ash

A weighed amount of the powder was taken in a silica crucible previously ignited, cooled and weighed. It was incinerated using incinerator by gradually increasing the heat not exceeding dull red heat (450°C) until free from carbon, cooled and weighed. The percentage of ash was calculated with reference to air-dried drug. The procedure was repeated to get constant weight.

Water soluble ash

The total ash was boiled with 25 ml water and filtered through ash less filter paper (Whatmann 4.1). It was followed by washing with hot water. The filter paper was dried and ignited in a silica crucible, cooled and the water insoluble ash was weighed. The water-soluble ash was calculated by subtracting the water insoluble ash from the total ash.

Acid insoluble ash

The total ash obtained was boiled for 5 minutes with 25 ml of dilute hydrochloric acid (10% w/v) and filter through ash less filter paper (Whatmann No.1). The filter paper was ignited in a silica crucible, cooled and weighed.

Determination of Alcohol Soluble Extractive

The air dried drug was finely grounded, added with 100 ml of ethanol of specified strength in a closed flask for twenty-four hours, shaken frequently during

the course of six hours and allowed to stand for eighteen hours. Then the mixture was filtered rapidly taking precautions against loss of solvent, 25 ml of the filtrate was evaporated to dryness in a tarred flat bottomed shallow dish, and dried at 105º to constant weight. The percentage of alcohol-soluble extractive with reference to the air-dried drug was estimated.

The obtained RASA CHENDHURAM was given for instrumental analysis at cri arumbakkam Chennai

HEAVY METAL ANALYSIS

Heavy metal	Procedure	observation
Mercury	1. Add 5ml of hydrochloric acid to little substance, precipitate appears 2. Then boil the precipitate with water. It does not dissolves add sodium hydroxide solution .heat it and fillter	No black precipitaion appears
Lead	1.add 2ml of potassium chormate to salt solution.	No yellow precipitate appears
Arsenic	To 10 drops of solution. Add 6ml NH_3 until neutral.make the solution acidic b adding one or more drops of 6 M HCL. Add 1 ml of thioacetamide and stir well. Heat the test tube in the boiling water bath for 5 minutes	No red orange precipitate Or No Yellow or brown precipitates appears
Cadmium	add 2ml of solution, add 1 ml NaOH, add 1ml of distal water and add 1 ml of Hcl	No Yellow precipitates appears
Chromium	To 10 drops of solution, add 1ml of 3% H_2O_2 then add 6M NaOH dropwise untill the solution is basic. Heat in a boiling water bathh for a few minutes	No yellow solution of CrO_4^2 form

ACUTE ORAL TOXICITY STUDY OF *RASA CHENDHURAM (PULIPANI)* (OECD GUIDELINE – 423)

Introduction:

- The acute toxic class method is a stepwise procedure with the use of 3 animals of a single sex per step.
- Depending on the mortality and/or the moribund status of the animals, on average 2-4 steps may be necessary to allow judgement on the acute toxicity of the test substance.
- This procedure is reproducible, uses very few animals and is able to rank substances in a similar manner to the other acute toxicity testing methods.
- The acute toxic class method is based on biometric evaluations with fixed doses, adequately separated to enable a substance to be ranked for classification purposes and hazard assessment.
- In principle, the method is not intended to allow the calculation of a precise LD50, but does allow for the determination of defined exposure ranges where lethality is expected since death of a proportion of the animals is still the major endpoint of this test.
- The method allows for the determination of an LD50 value only when at least two doses result in mortality higher than 0% and lower than 100%.
- The use of a selection of pre-defined doses, regardless of test substance, with classification explicitly tied to number of animals observed in different states improves the opportunity for laboratory to laboratory reporting consistency and repeatability.

Principle of the Test:

It is the principle of the test that based on a stepwise procedure with the use of a minimum number of animals per step, sufficient information is obtained on the acute toxicity of the test substance to enable its classification. The substance is administered orally to a group of experimental animals at one of the defined doses. The substance is tested using a stepwise procedure, each step using three animals of a single sex. Absence or presence of compound-related mortality of the animals dosed at one step will determine the next step, i.e.

− no further testing is needed

− dosing of three additional animals, with the same dose

− dosing of three additional animals at the next higher or the next lower dose level. The method will enable a judgment with respect to classifying the test substance to one of a series of toxicity classes.

Methodology:

Selection of Animal Species

The preferred rodent species is the wistar albino rat, although other rodent species may be used. Healthy young adult animals are commonly used laboratory strains should be employed. Females should be nulliparous and non-pregnant. Each animal, at the commencement of its dosing, should be between 6 to 8 weeks old and the weight (150-200gm) should fall in an interval within±20 % of the mean weight of any previously dosed animals.

Housing and Feeding Conditions

The temperature in the experimental animal room should be 22ºC + 3ºC. Although the relative humidity should be at least 30% and preferably not exceed 70% other than during room cleaning the aim should be 50-60%. Lighting should be artificial, the sequence being 12 hours light, 12 hours dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. Animals may be group-caged by dose, but the number of animals per cage must not interfere with clear observations of each animal.

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions.

Test Animals and Test Conditions:

Sexually mature Female Wistar albino rats (150-200gm) were obtained from TANUVAS, Madhavaram, Chennai. All the animals were kept under standard environmental condition (22±3°C). The animals had free access to water and standard pellet diet (Sai meera foods, Bangalore).

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Preparation for Acute Toxicity Studies

Rats were deprived of food overnight (but not water 16-18 h) prior to administration of the, ***RASA CHENDHURAM (PULIPANI)***.

The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of the animals and the study design

IAEC No	**: IAEC/XL VIII/30/CLBMCP/2016**
Test Substance	: **RASA CHENDHURAM (PULIPANI)**
Animal Source	: TANUVAS,Madhavaram, Chennai.
Animals	: Wister Albino Rats (Female-3+3)
Age	**:** 6-8 weeks
Body Weight on Day 0	**:** 150-200gm.
Acclimatization	**:** Seven days prior to dosing.
Veterinary examination	**:** Prior and at the end of the acclimatization period.
Identification of animals	**:** By cage number, animal number and individual marking by using Picric acid.
Number of animals	: 3 Female/group,
Route of administration	: Oral
Diet	**:** Pellet feed supplied by Sai meera foods Pvt Ltd, Bangalore
Water	**:** Aqua guard portable water in polypropylene bottles.
Housing & Environment	**:** The animals were housed in Polypropylene cages provided with bedding of husk.
Housing temperature	**:** between 22ºC $\pm$ 3ºC.
Relative humidity	**:** between 30% and 70%,
Air changes	**:** 10 to 15 per hour and
Dark and light cycle	**:** 12**:**12 hours.
Duration of the study	**:** 14 Days

Administration of Doses:

RASA CHENDHURAM (PULIPANI) was suspended in water and administered to the groups of wistar albino rats in a single oral dose by gavage using a feeding needle. The control group received an equal volume of the vehicle. Animals were fasted 12 hours prior to dosing. Following the period of fasting, the animals were weighed and then the test substance was administered. Three Female animals are used for each group. The dose level of 9mg/kg body weight was administered. After the substance has been administered, food was withheld for a further 3-4 hours. The principle of laboratory animal care was followed. Observations were made and recorded systematically and continuously as per the guideline after substance administration. The visual observations included skin changes, mobility, aggressively, sensitivity to sound and pain, as well as respiratory movements. Finally, the number of survivors was noted after 24 hrs and these animals were then monitored for a further 14 days and observations made daily. The toxicological effect was assessed on the basis of mortality.

Observations:

Animals are observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours, and daily thereafter, for a total of 14 days, except where they need to be removed from the study and humanely killed for animal welfare reasons or are found dead. It should be determined by the toxic reactions, time of onset and length of recovery period, and may thus be extended when considered necessary. The times at which signs of toxicity appear and disappear are important, especially if there is a tendency for toxic signs to be delayed. All observations are systematically recorded with individual records being maintained for each animal.

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity and behavior pattern. Attention was directed to observations of tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. The principles and criteria summarized in the Humane Endpoints Guidance Document taken into consideration. Animals found in a moribund condition and animals showing severe pain or enduring signs of severe distress was humanly killed. When animals are killed for human reasons or found dead, the time of death was recorded.

Acute oral toxicity study of RASA CHENDHURAM (PULIPANI)

Table 1: Dose finding experiment and its behavioral Signs of acute oral Toxicity

Observation done:

SL	Group CONTROL	Observation	SL	Group TEST GROUP	Observation
1	Body weight	Normal	1	Body weight	Normally increased
2	Assessments of posture	Normal	2	Assessments of posture	Normal
3	Signs of Convulsion Limb paralysis	Normal	3	Signs of Convulsion Limb paralysis	Absence of sign (-)
4	Body tone	Normal	4	Body tone	Normal
5	Lacrimation	Normal	5	Lacrimation	Absence
6	Salivation	Normal	6	Salivation	Absence
7	Change in skin color	No significant color change	7	Change in skin color	No significant color change
8	Piloerection	Normal	8	Piloerection	Normal
9	Defecation	Normal	9	Defecation	Normal
10	Sensitivity response	Normal	10	Sensitivity response	Normal
11	Locomotion	Normal	11	Locomotion	Normal
12	Muscle gripness	Normal	12	Muscle gripness	Normal
13	Rearing	Mild	13	Rearing	Mild
14	Urination	Normal	14	Urination	Normal

Behaviour:

The animals will be observed closely for behaviour in the first four hours which includes abnormal gait, aggressiveness, exophthalmos, ptosis, akinesia, catalepsy, convolusion, excitation, head twitches, lacrimation, loss of corneal reflex, loss of traction, piloerection reactivity of touch, salivation, scratching, sedation, chewing, head movements, sniffing, straub, tremor and writhes, diarrhea, leathery, sleep and coma.

Body Weight:

Individual weight of animals was determined before the test substance was administered and weights will be recorded at day 1, 7, and 14 of the study. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and humanly killed.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Mortality:

Animals were observed for mortality throughout the entire period.

REPEATED DOSE 28-DAY ORAL TOXICITY (407) STUDY OF *RASA CHENDHURAM (PULIPANI)*

Test Substance	: **RASA CHENDHURAM (PULIPANI)**
Animal Source	: TANUVAS,Madhavaram, Chennai.
Animals	: Wister Albino Rats (Male -24, and Female-24)
Age	**:** 6-8 weeks
Body Weight	**:** 150-200gm.
Acclimatization	**:** Seven days prior to dose.
Veterinary examination	**:** Prior and at the end of the acclimatization period.
Identification of animals	**:** By cage number, animal number and individual marking by using Picric acid
Diet	**:** Pellet feed supplied by Sai meera foods Pvt Ltd, Bangalore

Water **:** Aqua guard portable water in polypropylene bottles.

Housing & Environment **:** The animals were housed in Polypropylene cages provided with bedding of husk.

Housing temperature **:** between 22ºC ± 3ºC.

Relative humidity **:** between 30% and 70%,

Air changes **:** 10 to 15 per hour

Dark and light cycle **:** 12**:**12 hours.

Duration of the study **: 28 Days.**

Table 5

Groups	**No of Rats**
Group I Vehicle control (Water)	12(6male,6 female)
Group II RCMp- low dose X (9mg)	12 (6male,6 female)
Group III RCMp- Mid dose 5X (45mg)	12 (6male,6female)
Group IV RCMp- High dose 10X(90mg)	12(6male,6female)

RCM - RASA CHENDHURAM (PULIPANI)

Methodology

Randomization, Numbering and Grouping of Animals:

48 Wistar Albino Rats (24M + 24F) were selected and divided into 4 groups. Each group consist of 12 animals (Male -6, and Female-6). First group treated as a control and other three group were treated with test drug (low, mid, high) for 28 days. Animals were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal was marked with picric acid. The females were nulliparous and non-pregnant.

Justification for Dose Selection:

As per OECD guideline three dose levels were selected for the study. They are low dose (X), mid dose dose (5X), high dose (10X). X is calculated by multiplying the therapeutic dose (488mg) and the body surface area of the rat (0.018). i.e X dose is (9mg), 5X dose is 45mg/animal, 10X dose is 90mg/animal.

Preparation and Administration of Dose:

RASA CHENDHURAM (PULIPANI) suspended in prescribed solvent, It was administered to animals at the dose levels of X, 5X, 10X. The test substance suspensions were freshly prepared every two days once for 28 days. The control animals were administered vehicle only. The drug was administered orally by using oral gavage once daily for 28 consecutive days.

Observations:

Experimental animals were kept under observation throughout the course of study for the following:

Body Weight:

Weight of each rat was recorded on day 0, at weekly intervals throughout the course of study.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Clinical signs:

All animals were observed daily for clinical signs. The time of onset, intensity and duration of these symptoms, if any, were recorded.

Mortality:

All animals were observed twice daily for mortality during entire course of study.

Necropsy:

All the animals were sacrificed by excessive anaesthesia on day 29. Necropsy of all animals was carried out.

Laboratory Investigations:

Following laboratory investigations were carried out on day 29 in animals fasted over-night. Blood samples were collected from orbital sinus using sodium heparin (200IU/ml) for Bio chemistry and potassium EDTA (1.5 mg/ml) for Hematology as anticoagulant. Blood samples were centrifuged at 3000 r.p.m. for 10 minutes.

Haematological Investigations:

Haematological parameters were determined using Haematology analyzer.

Biochemical Investigations:

Biochemical parameters were determined using auto-analyzer.

Histopathology:

Control and highest dose group animals will be initially subjected to histopathological investigations. If any abnormality found in the highest dose group than the low, then the mid dose group will also be examined. Organs will be collected from all animals and preserved in 10% buffered neutral formalin for 24 h and washed in running water for 24 h. The organ sliced 5 or 6µm sections and were dehydrated in an auto technicon and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" moulds. It was followed by microtome and the slides were stained with Haematoxylin-eosin red.

Statistical analysis:

Findings such as body weight changes, water and food consumption, hematology and blood chemistry were subjected to One-way ANOVA followed by dunnet t test using a computer software programme – Graph pad version 7.All data were summarized in tabular form, (Table-6 to 12)

STUDY DESIGN:

An Open Comparative Clinical Trial

STUDY PLACE :

OPD section of post graduate, sirappu maruthuvam department attached to Arignar Anna Government Hospital, Government Siddha Medical College, Arumbakkam, Chennai.

DATA COLLECTION:

Literary evidence collected from various

- Siddha literatures
- Books on modern medicine

TRIAL DRUGS:

INTERNAL DRUG: RASA CHENDHURAM , 65 mg , twice daily.

EXTERNAL DRUG: PALAGARAI KUZHAMBU

SAMPLE SIZE:

40 cases OPD

- 20 patients treated with internal drug alone
- 20 patients treated with internal and external drugs

INCLUSION CRITERIA

- Age: Between 18 - 60 years.
- Sex: Both male and female
- Hypo-pigmented patches with hyper pigmented border without any structural changes in any part of the body
- Patient Willing to sign consent form.
- Hypopigmentation due to Worm infestation

EXCLUSION CRITERIA

- Albinism
- Leprosy
- STD
- HIV
- Burns
- Pregnancy and Lactation
- Cardiac diseases
- History of long term use of steroids.

WITHDRAWAL CRITERIA

- Intolerance to the drug and development of adverse reactions during the period of drug trial.

Poor patient compliance & defaulters resulting in adverse events.

ADR REPORTING

If ADR is reported patients will be referred to SCRI (Peripheral Pharmaco vigilance centre)

EVALUATION OF CLINICAL PARAMETERS:

Patients are clinically evaluated by the following parameters.

HISTORY TAKING:

Age , sex, occupation , socio economic status, complaints and its duration , previous illness , family history , personal habits were recorded in the case shet for every patient at the time of first visit to OP.

MODERN INVESTIGATIONS:

Blood:

Hb, TC, DC, ESR, Blood sugar (R)

Kidney Function Tests:

Blood Urea, Serum Creatinine

Liver Function Tests:

Direct Bilirubin,

Serum total bilirubin,

In Direct bilirubin,

SGOT, SGPT

Urine:

Albumin,

Sugar

Deposits

ASSESSMENT TOOLS

A. Clinical assessment:

VITILIGO AREA SEVERITY INDEX (VASI):

Its name is an adoption from PASI score in psoriasis. The percentage of vitiligo involvement is calculated in terms of hand units. One hand unit is approximately equivalent to 1% of the total body surface area. The degree of pigmentation is estimated to the nearest of one of the following percentages: 100% - complete depigmentation, no pigment is depigmentation]present; 90% - specks of pigment present; 75% - depigmented area exceeds the pigmented area; 50% - pigmented and depigmented areas are equal;

25% - pigmented area exceeds depigmented area; and 10% - only specks of depigmentation present . The VASI for each body region is determined by

the product of the area of vitiligo in hand units and the extent of depigmentation within each hand unit measured patch.

Total body VASI = S All body sites [Hand Units] ´ [Residual depigmentation] [1].

The VASI for each body region is determined by the product of the area of vitiligo in hand units and the extent of depigmentation within each hand unit measured patch.

Total body VASI = S All body sites [Hand Units] ´ [Residual depigmentation] [1].

VASI score	~−50	Very much worse
VASI score	-50 -25	Much worse
VASI score	-26 -10	Worse
VASI score	-10 0	Minimally worse
VASI score	0 10	Minimally improved
VASI score	10 25	Improved
VASI score	25 50	Much improved
VASI score	+50~	Very much improved

CALCULATION:

The body is divided into four sections (head (H) (10% of a person's skin); arms (A) (20%); trunk (T) (30%); legs (L) (40%)). Each of these areas is scored by itself, and then the four scores are combined into the final PASI. For each section, the percent of area of skin involved, is estimated and then transformed into a grade from 0 to 6:

- 0% of involved area, grade: 0
- < 10% of involved area, grade: 1
- 10–29% of involved area, grade: 2
- 30–49% of involved area, grade: 3
- 50–69% of involved area, grade: 4
- 70–89% of involved area, grade: 5
- 90–100% of involved area, grade: 6

Within each area, the severity is estimated by three clinical signs: erythema (redness), induration (thickness) and desquamation (scaling). Severity parameters are measured on a scale of 0 to 4, from none to maximum.

The sum of all three severity parameters is then calculated for each section of skin, multiplied by the area score for that area and multiplied by weight of respective section (0.1 for head, 0.2 for arms, 0.3 for body and 0.4 for legs).

B. Photo assessment:

Photos of the patient before and after treatment for clinical improvement evidence.

DRUG STORAGE:

The trial drug is stored in clean air tight glass container (borosil container) and it is dispensed to the patients.

DATA COLLECTION FORMS:

Required information will be collected from each patients by using following forms.

Form I : Screening and selection proforma
Form II : History taking proforma
Form III : Clinical assessment proforma
Form IV : Clinical assessment during and after trial
Form V : Laboratory investigation proforma
Form VI : Informed consent form
Form VII : Withdrawal form
Form VIII : Patients information sheet

STUDY ENROLLMENT

In this study Patients reporting at the OPD with the clinical symptoms of Hypo pigmentation, itching, burning sensation etc will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who are to be enrolled would be informed (Form IV) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them.

After ascertaining the patient's willingness, informed consent would be obtained in writing from them in the consent form (Form IV). All these patients will be given unique registration card in which patients Registration number of the study, Address, Phone number and Doctors phone number etc. will be given, so as to report easily should any complications arise.

Complete clinical history, complaints and duration, examination findings-- all would be recorded in the prescribed Proforma in the history and clinical assessment forms separately. Screening Form- I will be filled up: Form –II and Form –III will be used for recording the patients history, clinical examination of symptoms and signs and laboratory investigations respectively. Patients would be advised to take the trial drug and appropriate dietary advice (Form IV-D) would be given according to the patients perfect understanding.

CONDUCT OF THE STUDY:

Patients satisfying the inclusion and exclusion criteria will be included in the trial.

Modern investigations will be carried out before treatment and at the end of the treatment. Photos will be taken before and after the treatment.

At the end of the study the trial patients are advised to report when there is reoccurrence.

DATA ANALYSIS:

After enrolling the patients in the study, a separate file for each patient will be maintained and all forms will be kept in the file. Whenever the patients visits OPD during the study period necessary entries will be made in the assessment forms. The data entries and adverse events if any will be monitored by the head of the department.

Primary Outcome

- The therapeutic efficacy of trial drugs will be assessed by repigmentation and also by reduction in the size.
- VASI Score (Vitiligo area scoring index)
- To evaluate the prevention of recurrence by follow-up after two months from the start of intervention.

  To evaluate the days of outcome with in the treatment of 48 days.

Secondary Outcome:

Secondary outcome is assessed by comparing the safety parameters before and after treatment.

ADR REPORTING

If ADR is reported patients will be referred to SCRI (Peripheral Pharmaco vigilance centre)

ETHICAL ISSUES:

- Informed consent will be obtained from the patients after explaining about the clinical trial in regional tongue.
- After the consent of the patient (through consent form) if they are in the inclusion criteria they will be enrolled in the study.
- Treatment will be provided free of cost.
- Concomitant medications will be given when required.
- Rescue medications will be given when needed.
- The patients who are excluded (as per exclusion criteria) are given proper treatment with full care at OPD.

RESULTS AND OBSERVATION

RASA CHENDHURAM ORGANOLEPTIC CHARACTORS

CHARACTERS	RESULTS
Colour	Dark red
Odour	Oderless
Taste	Tasteless
Appearance	Fine powder
Solubility	Sparingly soluble in both water and alcohol

COLOR OF THE INGREDIENTS

S.NO	RAW DRUGS	BEFORE PURIFICATION	AFTER PURIFICATION
1	Gandhagam	Yellow solid	Yellow granules
2	Rasam	Colourless, dust floated	Colourless
3.	Thalagam	Bright yellow	Yellow

RASA CHENDHURAM - PHYSICOCHEMICAL ANALYSIS RESULT

S.NO	NAME OF EXPERIMENT	VALUE
1	Loss on drying	0 %
2.	Total ash	91.5 %
3.	Water soluable ash	29 %
4.	Acid insoluable ash	48 %
5.	pH value (10%)	1.47

TRADITIONAL TESTING METHODS FOR CHENDHURAM

S.NO	TESTS	INFERENCE
1.	Floating on water	+
2.	Finger furrows test	+
3.	Lusterless	+
4.	Tasteless	+
5.	Colour	Dark red

QUALITATIVE ANALYSIS OF HEAVY METALS

S.NO	HEAVY METAL	RESULT
1	**LEAD**	**ND**
2	**MERCURY**	**ND**
3	**ARSENIC**	**ND**
4	**CADMIUM**	**ND**

ACUTE ORAL TOXICITY STUDY OF *RASA CHENDHURAM (PULIPANI)*

Results:

All data were summarized in tabular form, (Table-1-4) showing for each test group the number of animals used, the number of animals displaying signs of toxicity, the number of animals found dead during the test ,description of toxic symptoms,, weight changes, food and water intake

No of animals in each group:3

Table 2 (Observational study Results)

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	**Control**	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2.	**9mg**	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

1. Alertness 2. Aggressive ness 3. Pile erection 4. Grooming 5.Gripping 6. Touch Response 7. Decreased Motor Activity 8.Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12.Muscle relaxant 13. Hypnosis 14.Analgesia 15.Lacrimation 16.Exophthalmos 17.Diarrhea 18. Writhing 19. Respiration 20. Mortality.

(+ Present, - Absent)

Table 3 (Body weight Observation)

DOSE	DAYS		
	1	7	14
CONTROL	280.2±42.30	281.4 ± 64.12	282.6 ±26.18
HIGH DOSE	280.4± 21.24	281 ± 3.64	281.4 ± 2
P value (p)*	NS	NS	NS

Table 3 (Water intake (ml/day) of Wistar albino rats group exposed to *RASA*

CHENDHURAM (PULIPANI):

DOSE	DAYS		
	1	6	14
CONTROL	61 ± 1.12	62±2.22	63.9±1.14
HIGH DOSE	62.2±1.1	63±1.14	64.20±24
P value (p)*	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 4: Food intake (gm/day) of Wistar albino rats group exposed to *RASA CHENDHURAM (PULIPANI)*

DOSE	DAYS		
	1	7	14
CONTROL	56.24±2.22	56.2±7.42	58.4±3.46
High DOSE	60.6±1.63	60.6±2.62	64.1±5.38

RESULTS

Repeated Dose 28- day oral toxic study of RASA CHENDHURAM (PULIPANI)

Table 6: Body weight of wistar albino rats group exposed to *RASA CHENDHURAM (PULIPANI)*

DOSE	DAYS				
	1	7	14	21	28
CONTROL	230.2±15.45	231.5 ± 25.15	231.5 ± 15.50	232.5± 15.16	232.4 ± 15.15
LOW DOSE	235.2 ± 15.15	235.7 ± 32.22	236.6± 46.14	236 ± 62.18	236.41± 15.24
MID DOSE	200.4± 06.64	200.3 ± 16.24	201.2 ± 18.12	201.2 ± 11.26	202.4 ± 24.10
HIGH DOSE	210.6± 24.24	210.6 ± 10.42	211.4 ± 12.24	211 ± 14.38	212 ± 54.61
P value (p)*	NS	NS	NS	NS	NS

NS- Not Significant, **(p > 0.01),*(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 7: Water intake (ml/day) of Wistar albino rats group exposed to *RASA CHENDHURAM (PULIPANI)*

DOSE	DAYS				
	1	6	14	21	28
CONTROL	50.1 ± 4.32	50±4.12	50.2±1.10	50±1.12	50.4±1.12
LOW DOSE	52.1±1.11	52.8±2.22	52.6±1.42	53.2±2.26	52.4±1.21
MID DOSE	53.1±1.12	53.3±1.11	53.1±2.21	53.4±1.12	53.4±1.42
HIGH DOSE	54.1±1.41	54.2±1.42	54.4±1.44	54.6±1.52	55.8±2.82
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 8: Food intake (gm/day) of Wistar albino rats group exposed to *RASA CHENDHURAM (PULIPANI)*

DOSE	DAYS				
	2	7	23	22	28
CONTROL	30±5.14	31.2±2.12	31.3±2.18	31.2±1.14	32±2.12
LOW DOSE	30.2±1.14	31.3±1.31	31.1±1.21	31.5±1.32	31.5±1.62
MID DOSE	32.1±2.22	32.2±3.40	32.2±2.24	32.2±2.16	33.2±1.24
HIGH DOSE	33.1±1.12	33.1±1.14	33.6±2.26	34.2±1.10	34.6±3.42
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test

Table 9: Haematological parameters of Wistar albino rats group exposed to *RASA CHENDHURAM (PULIPANI)*

Category	Control	Low dose	Mid dose	High dose	P value (p)*
Haemoglobin(g/dl)	16.7±0.71	16.60±0.24	16.5±0.23	16.82±0.16	N.S
Total WBC ($\times 10^3$ l)	10.81±0.32	10.64±0.21	10.54±0.42	9.60±1.12	N.S
Neutrophils (%)	31.12±0.01	31.02±0.12	32.11±1.22	33.02±6.21	N.S
lymphocyte (%)	72.12±1.24	72.12±1.32	73.10±2.34	73.20±2.44	N.S
Monocyte (%)	0.9±0.02	0.9±0.01	0.9±0.04	0.9±0.03	N.S
Eosinophil (%)	0.5±0.03	0.5±0.04	0.5±0.05	0.5±0.08	N.S
Platelets cells10^3/µl	680.17±3.13	682.41±4.12	682.13±2.02	684.10±2.34	N.S
Total RBC 10^6/µl	8.42±0.12	8.46±0.53	8.49±0.44	8.74±0.46	N.S
PCV%	42.12±0.2	42.62±1.02	43±1.20	44.40±2.10	N.S
MCHC g/dL	34.5±1.20	34.2±1.10	34.8±1.70	34.33±1.30	N.S
MCV fL(µm^3)	58.2±4.02	59.2±1.10	58.9±1.40	58.8±1.20	N.S

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 10 : Biochemical Parameters of of Wistar albino rats group exposed to *RASA CHENDHURAM (PULIPANI)*

BIOCHEMICAL PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
GLUCOSE (R) (mg/dl)	125.11±3.2	125.12±2.10	126.10±13.08	128.12±4.2	N.S
T.CHOLESTEROL(mg/dl)	120.16±1.20	120.25±1.30	122.60±1.18	123.24±1.30	N.S

TRIGLY(mg/dl)	54.16±1.52	54.12±1.42	56.15±1.23	56.16±1.23	N.S
LDL	72.4±2.14	72.12±2.54	73.10±1.32	73.24±10.20	NS
VLDL	11.2±1.30	11.20±2.21	11.22±1.24	11.14±12.14	NS
HDL	27.14±6.12	27.42±2.30	28.16±2.60	28.17±2.14	NS
Ratio 1(T.CHO/HDL)	3.41±1.16	3.42±1.40	3.74±1.04	3.64±2.03	NS
Ratio 2(LDL/HDL)	1.92±1.14	1.91±1.12	1.71±2.20	1.96±08.02	NS
Albumin (g/dL)	5.43±0.16	5.50±0.52	5.04±9.30	5.42±9.48	NS

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test

Table 11: Renal function test of of Wistar albino rats group exposed to *RASA CHENDHURAM (PULIPANI)*

PARAMETERS	**CONTROL**	**LOW DOSE**	**MID DOSE**	**HIGH DOSE**	**P Value (p)***
UREA (mg/dl)	26.70±0.19	26.50±0.26	27.16±1.28	27.68±1.24	N.S
CREATININE(mg/dl)	0.22±0.02	0.21±0.04	0.22±0.05	0.24±0.07	N.S
BUN(mg/dL)	17.1±0.01	17.10±0.64	17.6±0.52	17.86±1.02	NS
URIC ACID(mg/dl)	6.04±0.34	6.06±0.51	6.6±0.15	6.42±0.20	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05) , n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 12: Liver Function Test of of Wistar albino rats group exposed to Rasa Chendhuram (Pulipani)

PARAMETERS	**CONTROL**	**LOW DOSE**	**MID DOSE**	**HIGH DOSE**	**P Value (p)***
T BILIRUBIN(mg/dl).	0.07±0.01	0.07±0.02	0.07±0.01	0.07±0.03	N.S
SGOT/AST(U/L)	81.14±1.63	81.31±0.02	82.01±1.24	82.64±1.63	N.S

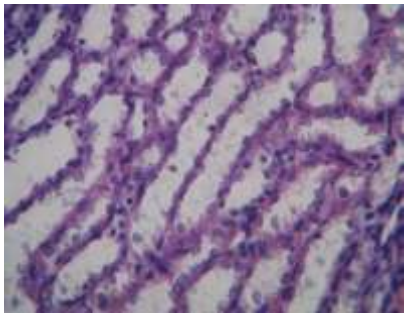
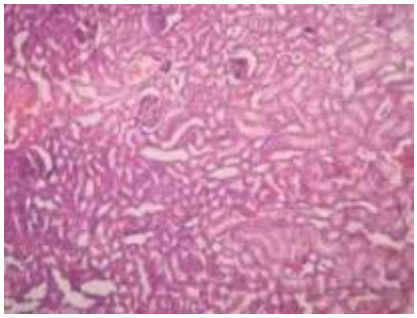
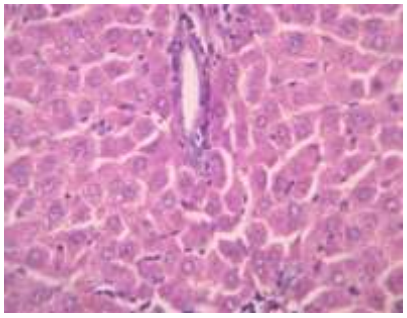
SGPT/ALT(U/L)	78.12±1.08	78.21±1.24	78.14±1.26	77.68±0.01	N.S
ALP(U/L)	119.21±3.16	119±32.10	119±12.14	120.03±8.32	N.S
T.PROTEIN(g/dL)	6.2.10±0.04	6.2±0.11	6.2±0.10	6.4±0.46	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test.

HISTO PATHOLOGY

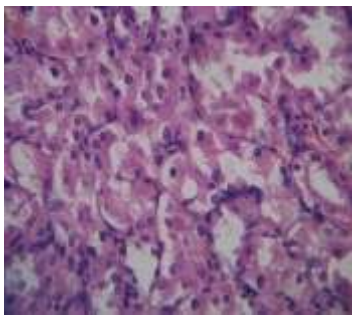
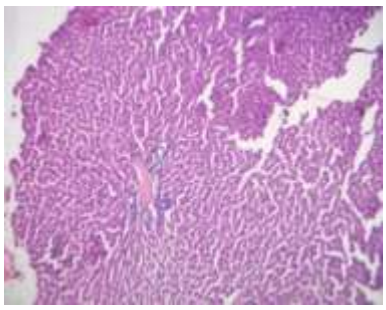
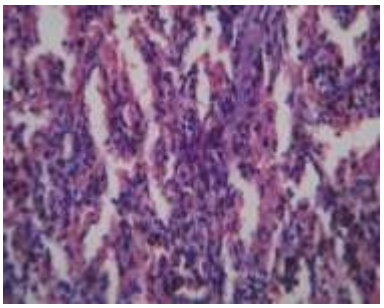
CONTROL GROUP

Kidney Liver Spleen

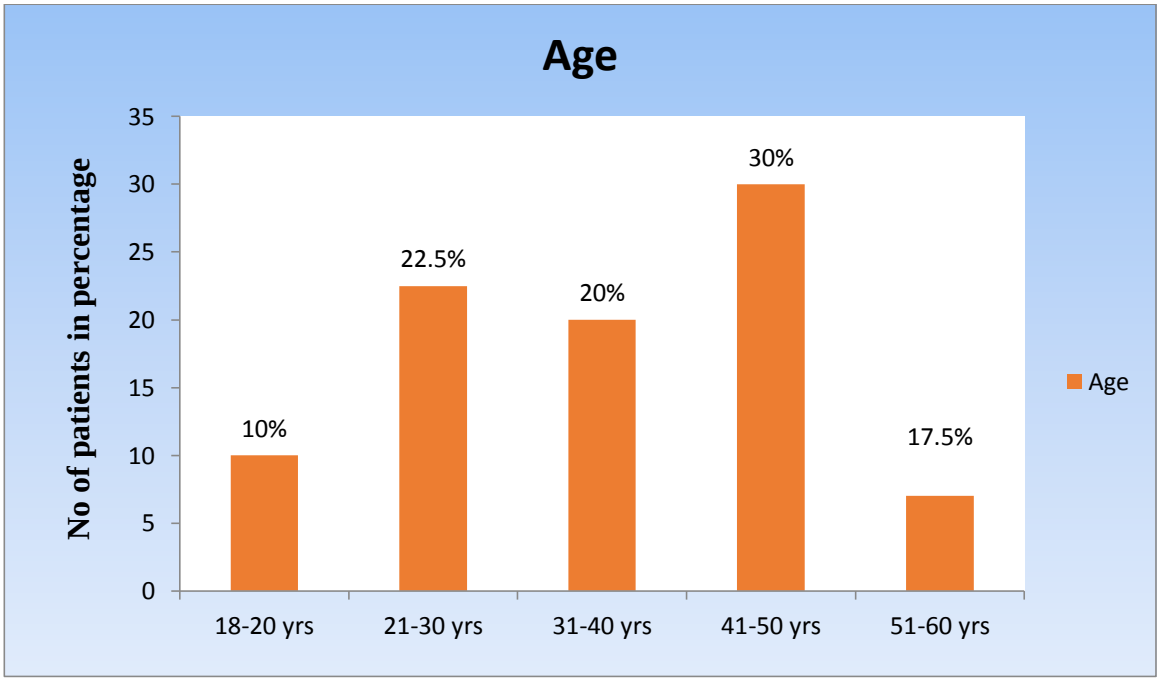
High dose

Kidney Liver Spleen

1. AGE

S. No	AGE(In years)	NO. OF CASES (Out of 40)	PERCENTAGE (%)
1.	18-20 Years	4	10%
2.	21-30 Years	9	22.5%
3.	31-40Years	8	20%
4.	41-50years	12	30%
5.	51-60years	7	17.5%

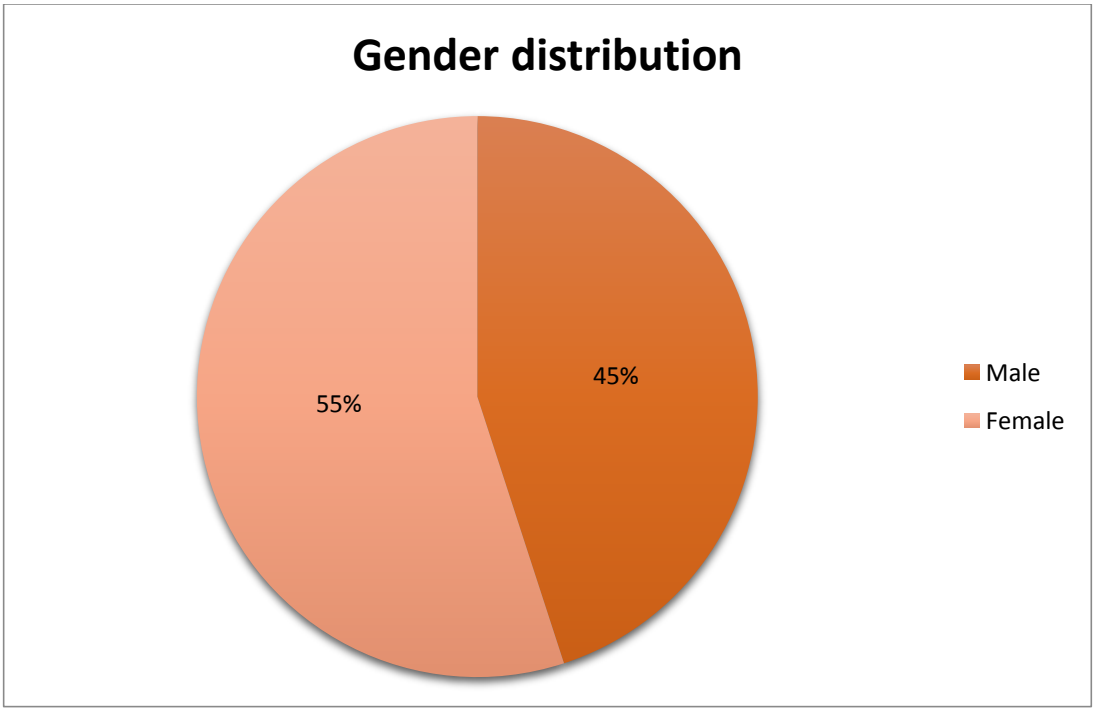


Inference:

Out of 40 cases, 4(10%) of cases belonged to the age group of 18-20 years, 9 (22.5%) of cases belonged to the age group of 21-30 years, 12 (30%) of cases belonged to the age group of 31-40 years, 11(27.5%) of cases belonged to the age group of 41-50 years, and 7(17.5%) of cases belonged to the age group of 51-60 years.

2. GENDER DISTRIBUTION

S. No	GENDER	NUMBER OF CASES	PERCENTAGE (%)
1	Male	18	45%
2	Female	22	55%

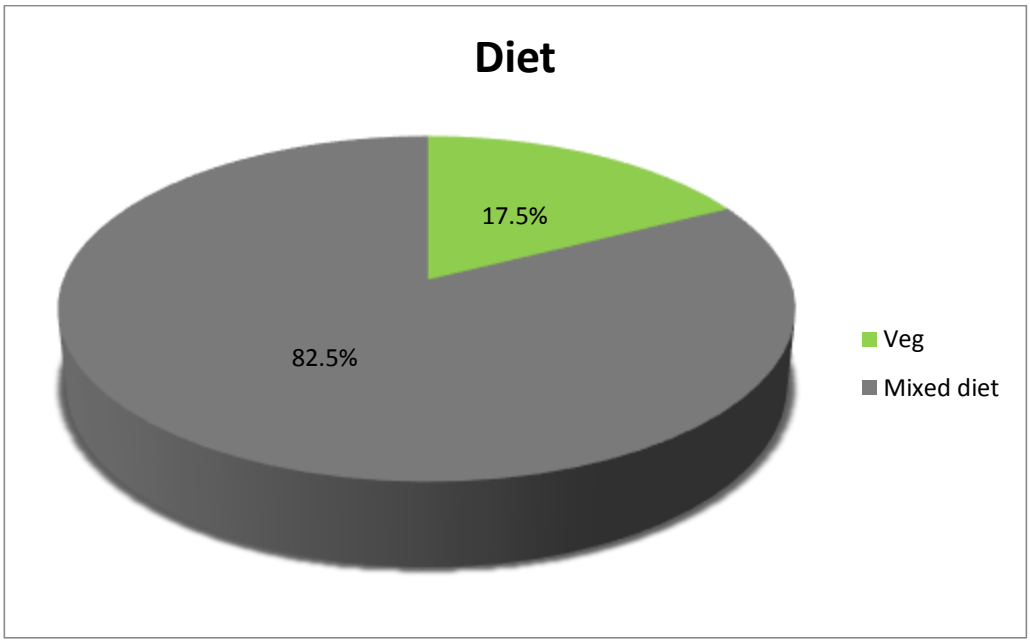


Inference:

Out of 40 cases, 18(45%) were Male, 22(55%) cases were Female.

3. DIETARY HABITS

S. No	DIET	NUMBER OF CASES	PERCENTAGE (%)
1	Vegetarian	7	17.5%
2	Mixed diet	33	82.5%

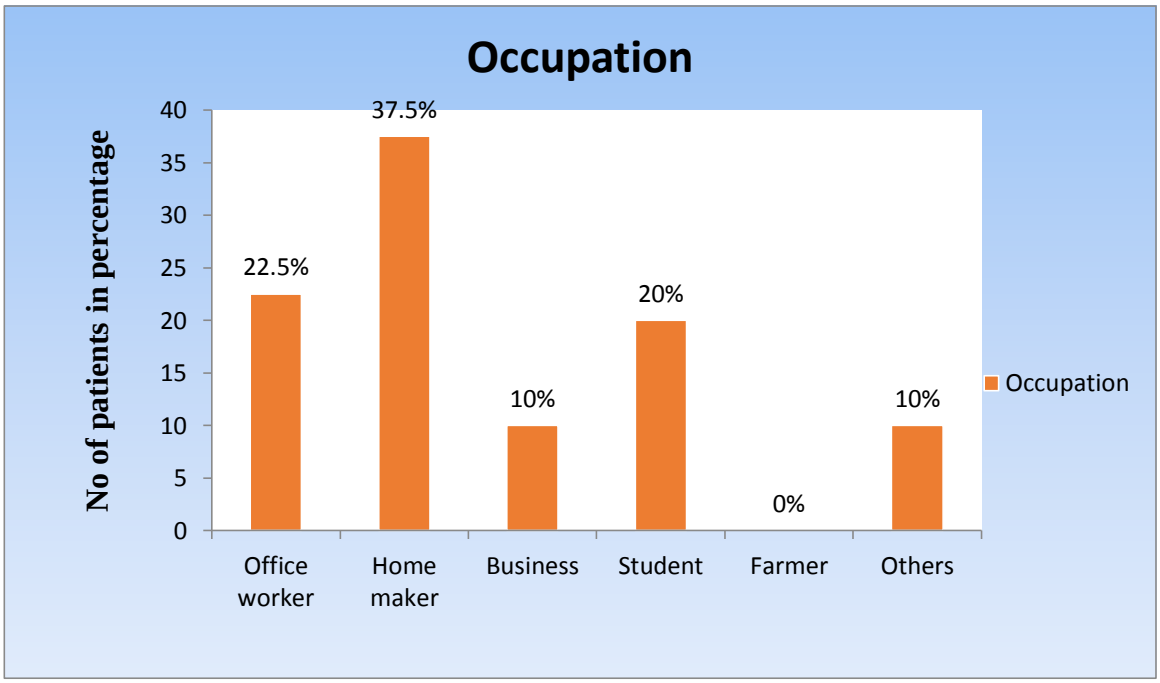


Inference:

Out of 40 cases 7 (17.5%) of cases were Vegetarians and 33 (82.5) cases were Non- vegetarians.

4. OCCUPATION

S.No	OCCUPATION	NUMBER OF CASES	PERCENTAGE (%)
1	Office worker	9	22.5%
2	Home maker	15	37.5%
3	Business	4	10%
4	Student	8	20%
5	Farmer	0	0%
6	Others	4	10%

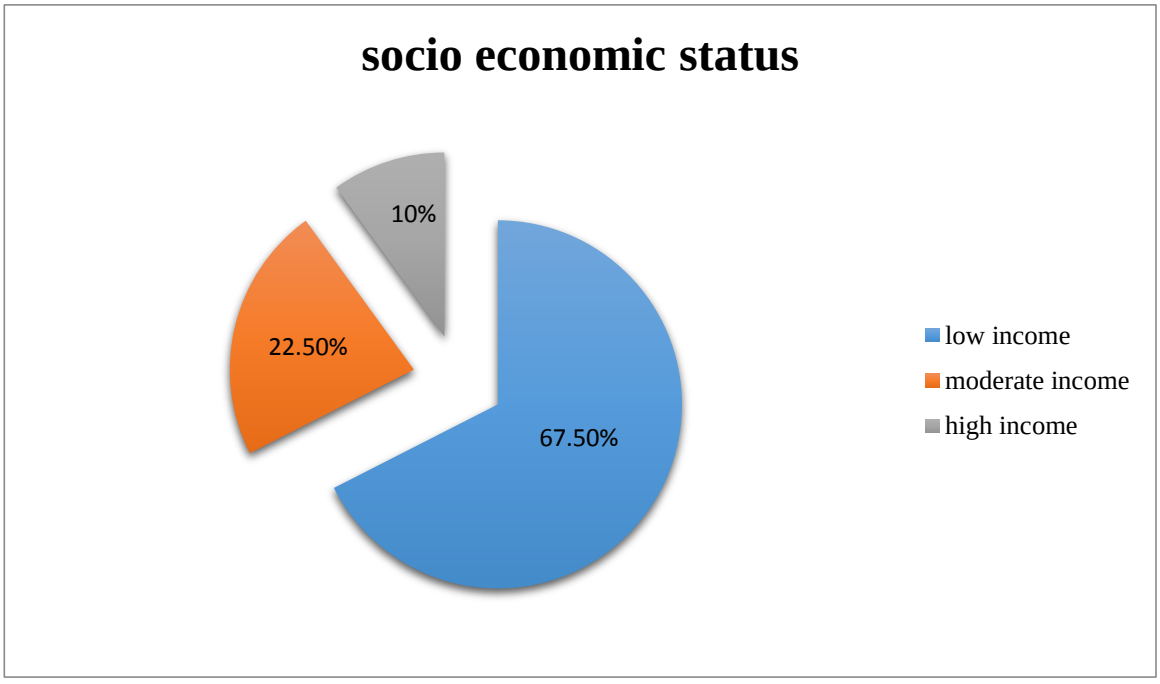


Inference:

Out of 40 cases 8 (20 %) were Student, 15 (37.5%) were Homemaker, 9 (22.5%) were Office Workers, 4 (10%)were businessmen, 0 (0 %) were farmer, 4 (10%) were others

5. SOCIO – ECONOMIC STATUS

S.No	SOCIO – ECONOMIC STATUS	NUMBER OF CASES	PERCENTAGE (%)
1	Low Income	27	67.5%
2	Moderate Income	9	22.5%
3	High Income	4	10%

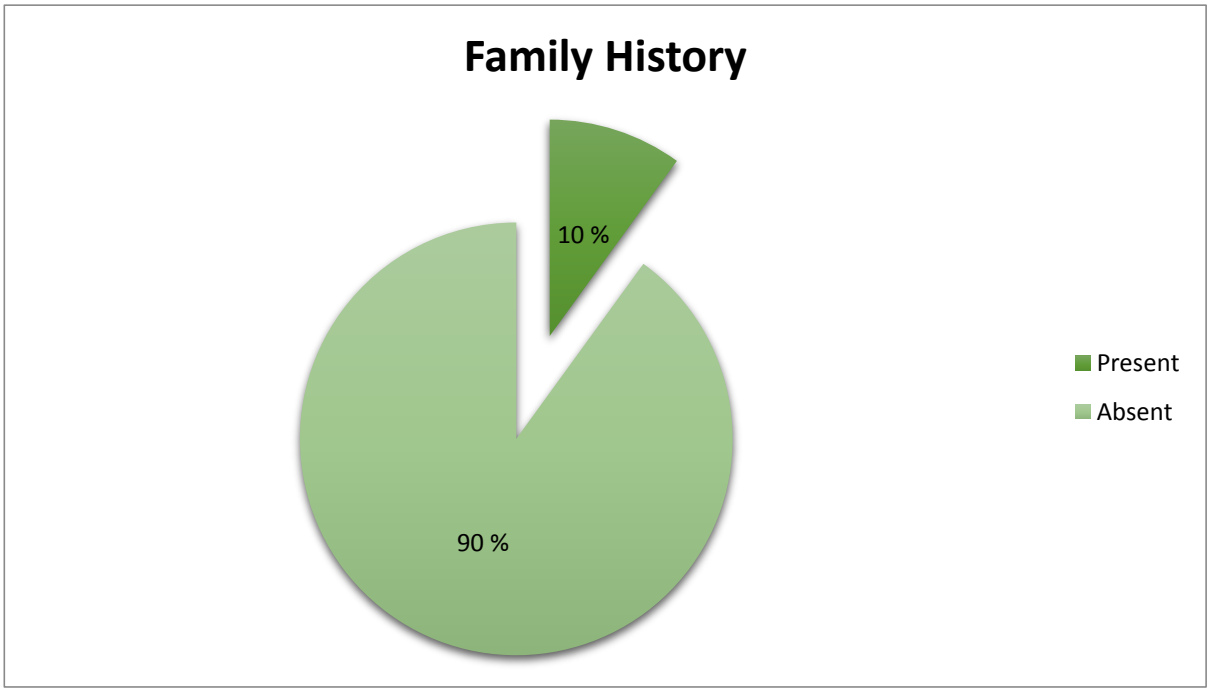


Inference:

Among 40 cases 67.5% comes under low economic status, 22.5% of them under moderate status and 10% of them under high income status.

6. FAMILY HISTORY:

FAMILY HISTORY	NUMBER OF CASES	PERCENTAGE
PRESENT	4	10%
ABSENT	36	90%

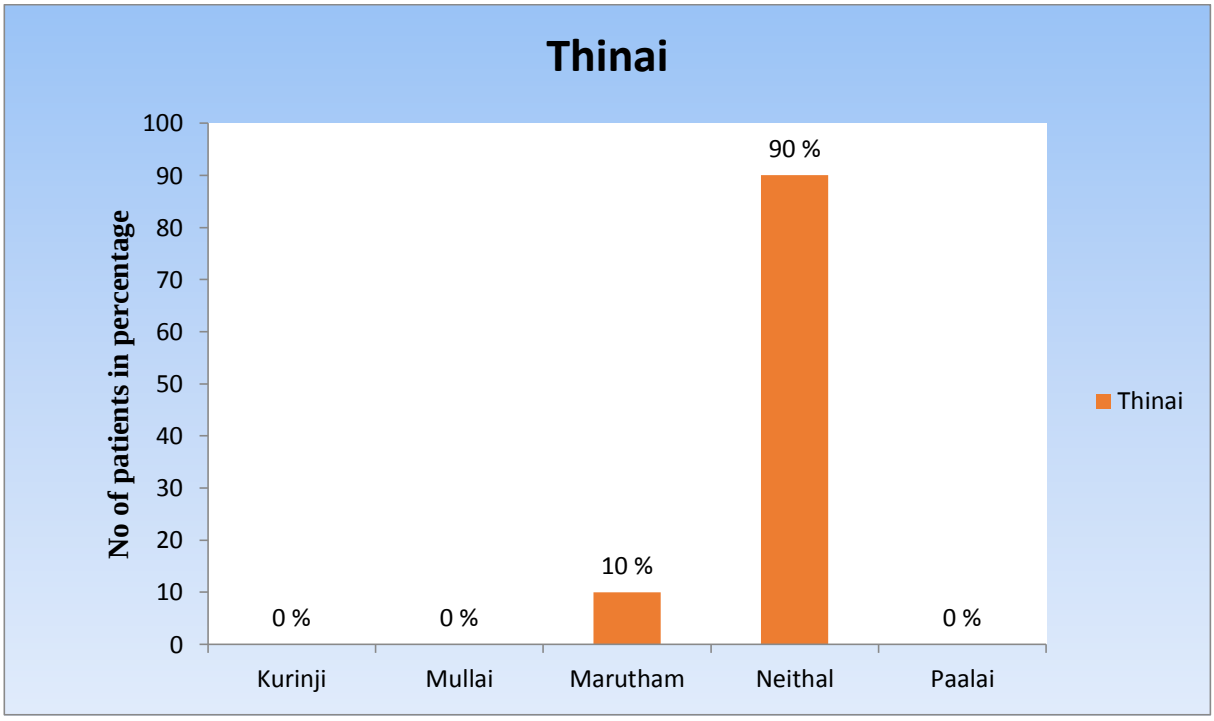


Inference:

Out of 40 cases 4 (10 %) of cases have family history and 36 (90%)of cases have no family history.

7 .DISTRIBUTION OF THINAI

S.No	THINAI	NUMBER OF CASES	PERCENTAGE (%)
1	Kurinji	0	0%
2	Mullai	0	0%
3	Marutham	4	10%
4	Neithal	36	90%
5	Paalai	0	0%

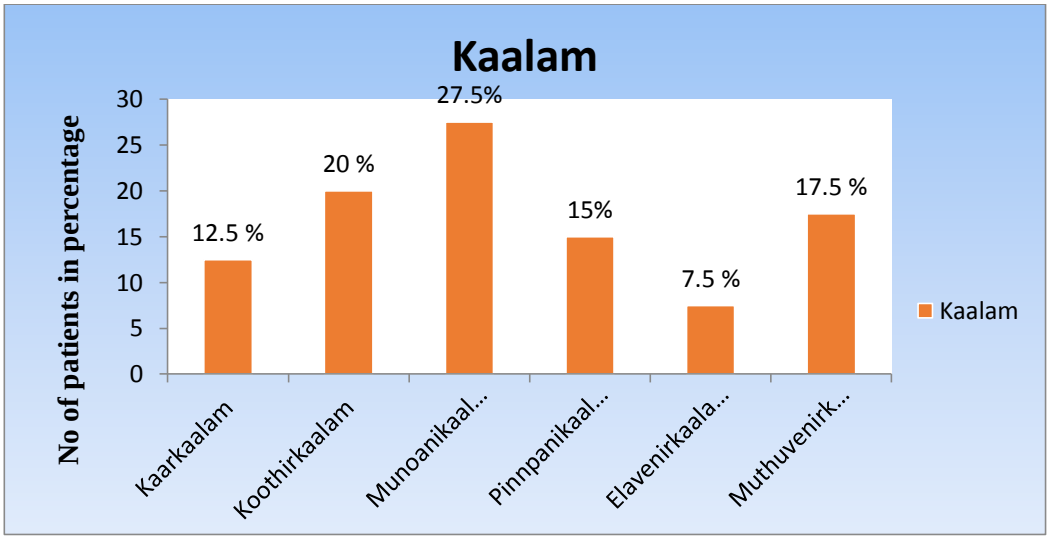


Inference:

Out the 40 patients, no patients were recorded from kurinchi ,mullai and Paalai thinai, 4(10%) of cases from Marutham thinai, 36(90%) from Neithal thinai.

8. PARUVAKAALAMDISTRIBUTION:

S.No	KAALAM (Season)	NUMBER OF CASES	PERCENTAGE (%)
1	Kaarkaalam (Mid Aug – Mid Oct)	5	12.5%
2	koothirKaalam (Mid Oct – Mid Dec)	8	20%
3	Munpanikaalam (Mid Dec – Mid Feb)	11	27.5%
4	Pinpanikaalam (Mid Feb – Mid Apr)	6	15%
5	Elavenirkaalam (Mid Apr – Mid Jun)	3	7.5%
6	Muthuvenirkaalam (Mid Jun – Mid Aug)	7	17.5%

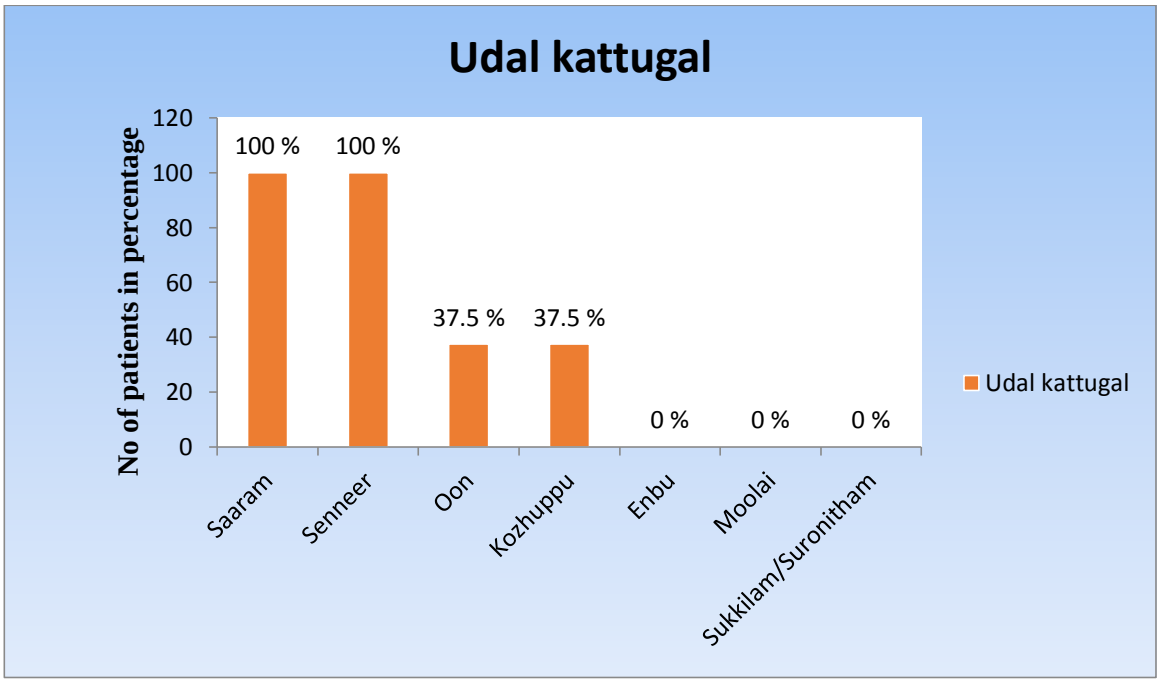


Inference:

Out of 40 cases, 5 patients (12.5 %) were recorded in Karkaalam, 8 patients (20%) were recorded in Koothir Kaalam, 11 patients (27.5%) were recorded in Munpani Kaalam, 6 patients (15%) were recorded in Pinpani Kaalam, 3 patients (7.5%) were recorded in Elavenil Kaalam and 7 patients (17.5%) were recorded in Mudhuvenil Kaalam.

9. EZHU UDALKATTUGAL

S.NO	UDAL KATTUGAL	No. ofCases	Percentage
1.	Saaram	40	100%
2.	Senneer	40	100%
3.	Oon	15	37.5 %
4.	Kozhuppu	15	37.5 %
5.	Enbu	-	-
6.	Moolai	-	-
7.	SukkilamSuronitham	-	-



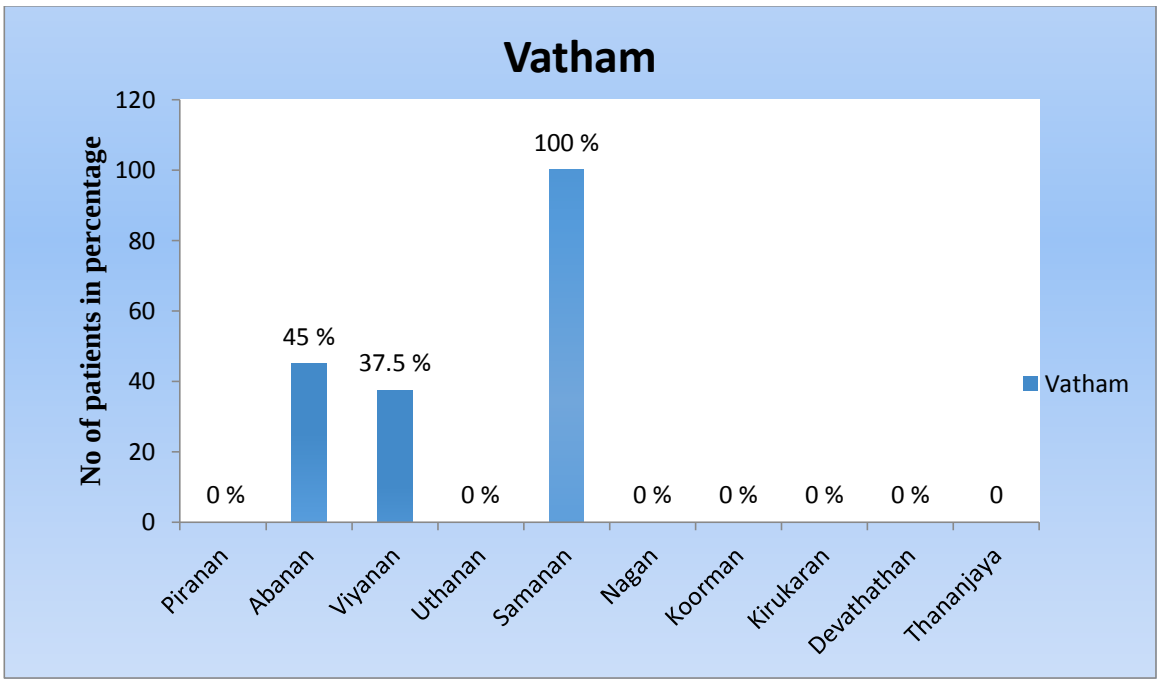
Inference:

Out of 40 cases Saaram was affected in all the 40 cases (100%), Senneer in 40 cases (75%) and oon in 15 cases , kozhuppu in 15 cases (37.5) and no other changes seen in other Udal Kattugal.

10. DISTRIBUTION OF MUKKUTRAM:

A. Derangement in the types of Vatham

S.No	Classification of vatham	No. of Cases	Percentage
1.	Piranan	-	-
2.	Abanan	18	45 %
3.	Viyanan	15	37.5%
4.	Uthanan	-	-
5.	Samanan	40	100
6.	Nagan	-	-
7.	Koorman		
8.	Kirukaran	-	-
9.	Devathathan	-	-



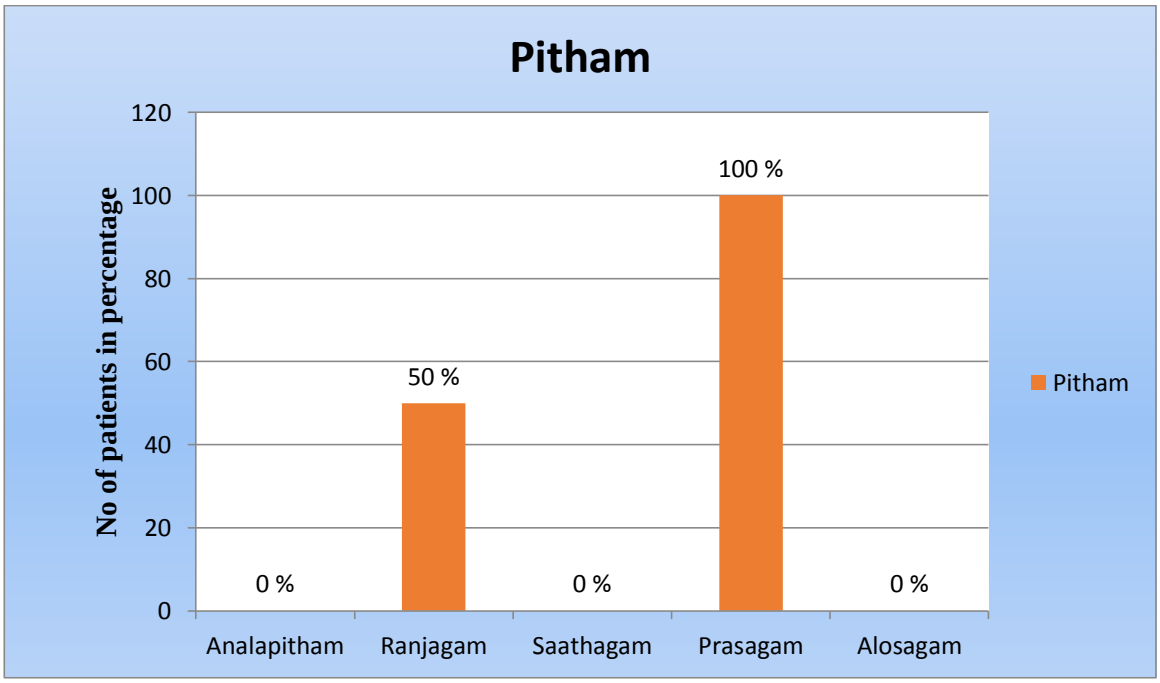
Inference:

A. Vatham:

Out of 40 cases Abanan was affected in 18 (45%) of cases. Viyanan was affected in 15 (37.5%) of cases and Samanan was affected in 40 (100%) of cases

B.Derangement in types of Pitham

S.No	Types of pitham	No. of Cases	Percentage
1.	Analapitham	-	-
2.	Ranjagam	20	50
3.	Saathagam	-	-
4.	Prasagam	40	100
5.	Alosagam	-	-

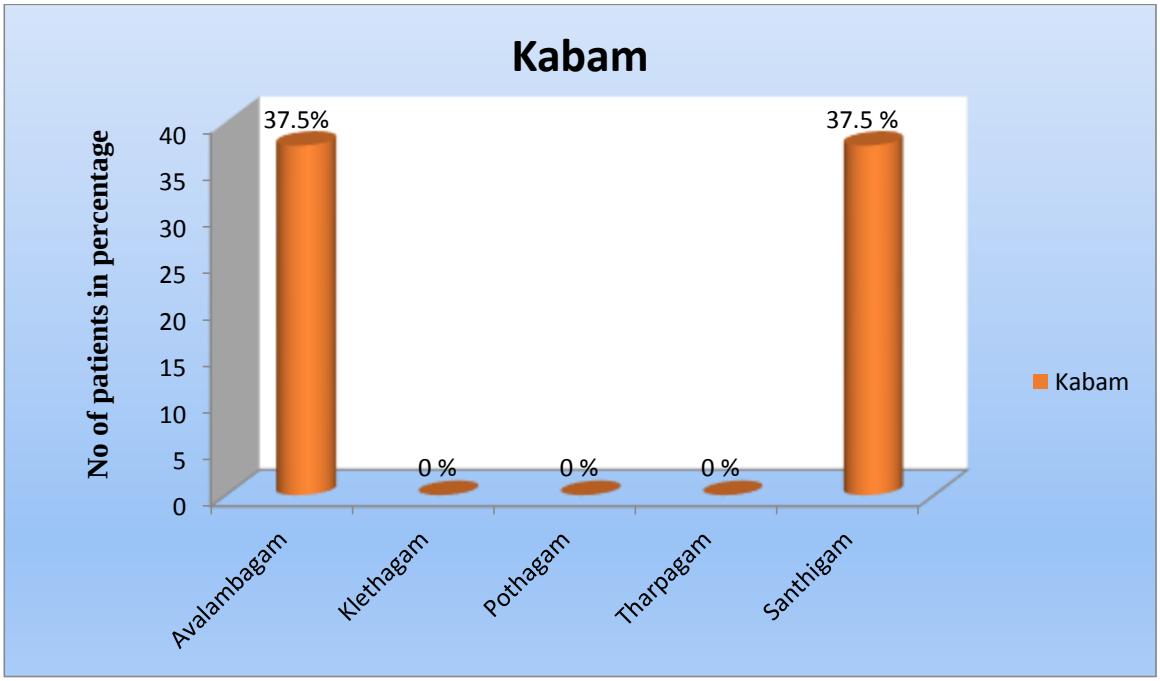


B.Inference:

Pitham: Ranjagam was affected in 20 of cases (50%) and Prasagam was affected in all the 40 (100%) of cases.

3. DERANGEMENT IN TYPES OF KABAM :

S.No	KABAM	NUMBER OF CASES	PERCENTAGE (%)
1	Avalambagam	15	37.5%
2	Klethagam	0	0%
3	Pothagam	0	0%
4	Tharpagam	0	0%
5	Santhigam	15	37.5%

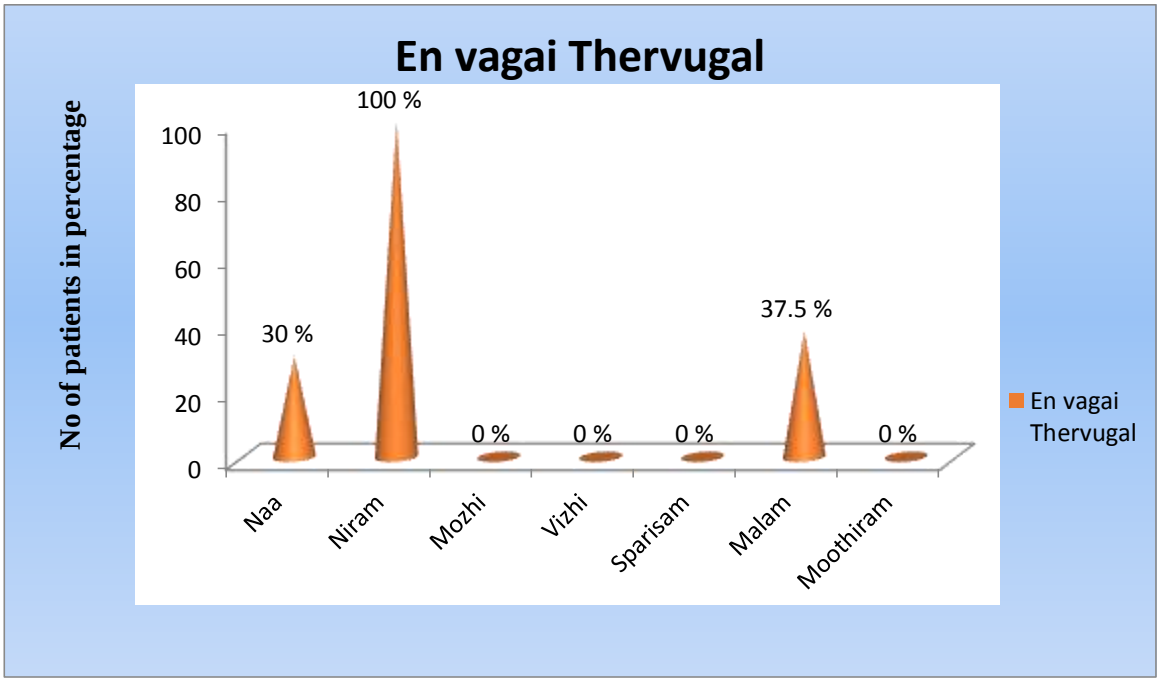


Inference:

Out of 40 patients, Avalambagam was affected in 15 patients (37.5%), Santhigam was affected in 15 patients (37.5%).

11. EN VAGAI THERVUGAL

S.No	EN VAGAI THERVUGAL	NUMBER OF CASES	PERCENTAGE (%)
1	Naa	12	30%
2	Niram	40	100%
3	Mozhi	0	0%
4	Vizhi	0	0%
5	Sparisam	0	0%
6	Malam	15	37.5%
7	Moothiram	0	0%

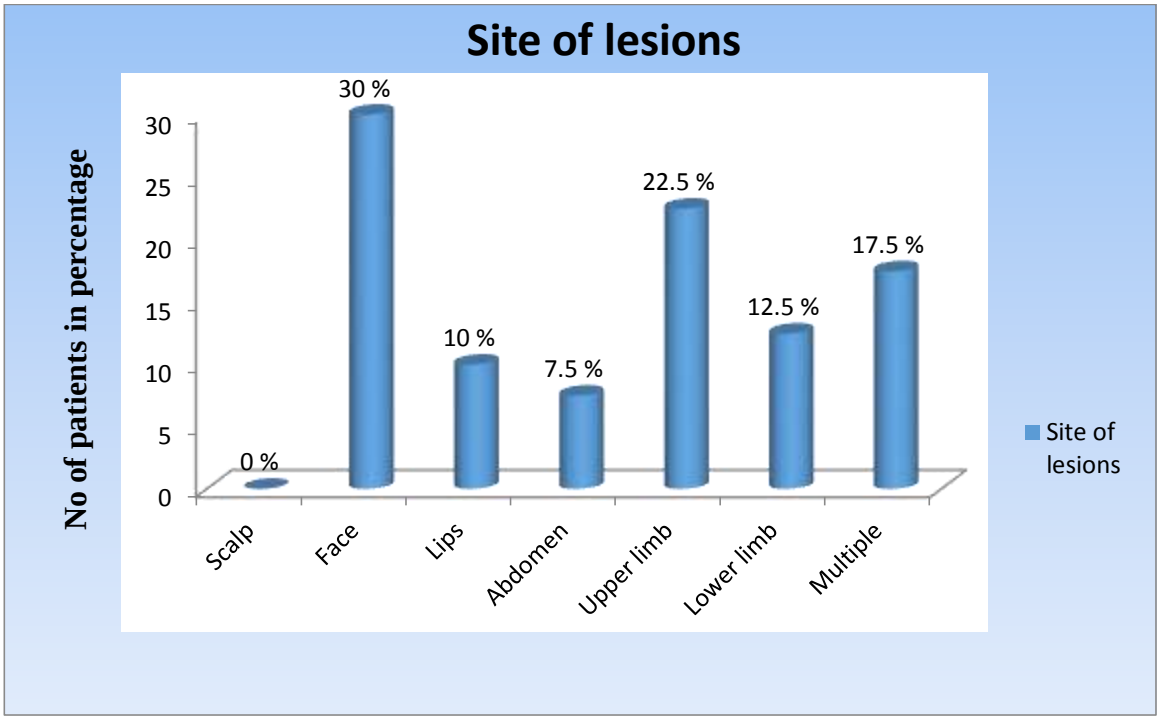


Inference:

Out of 40 patients, naa was affected in 12 cases (30 %) niram was affected in all the 40 (100%) cases; Malam was affected in 15 (37.5%) cases.

12 .SITE OF LESIONS :

SITE OF LESIONS	NO OF CASES OUT OF 40	PERCENTAGE(%)
Scalp	0	0%
Face	12	30%
Lips	4	10%
Abdomen	3	7.5%
Upper limb	9	22.5%
Lower limb	5	12.5%
Multiple	7	17.5%

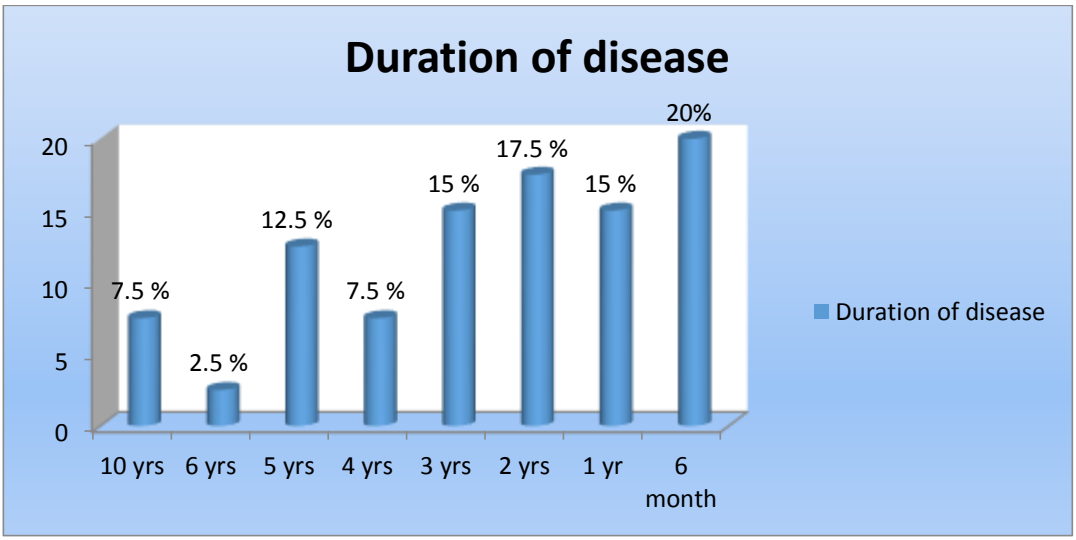


Inference :

Out of 40 patients 12 patients (30 %) were affected in the face , 3 patients (7.5%) were affected in the abdomen , 13 patients (7.5%) were affected in the upper limb , patients (12.5 %) were affected in the lower limb, 7 patients (17.5%) were affected in the multiple

13 .DURATION OF DISEASE

DURATION OF DISEASE	NO OF CASES	PERCENTAGE
10 Years	3	7.5%
6 Years	1	2.5%
5 Years	5	12.5%
4 Years	3	7.5%
3 Years	6	15%
2 Years	7	17.5%
1 Year	6	15%
6 Month	8	20%

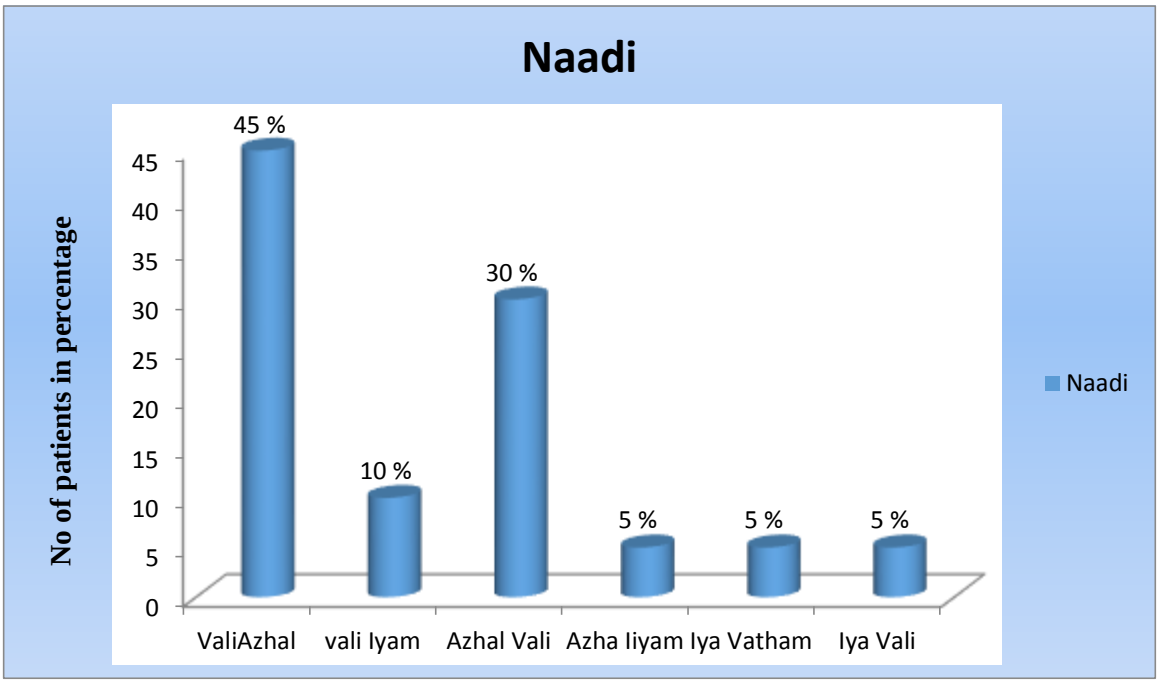


Inference:

The higher incidence of illness is 6 month of duration.

14 .NAADI

S.No	NAADI	NUMBER OF CASES	PERCENTAGE (%)
1	ValiAzhal	18	45%
2	ValiIyam	4	10%
3	AzhalVali	12	30%
4	AzhalIyam	2	5%
5	IyaVatham	2	5%
6	IyaVali	2	5%

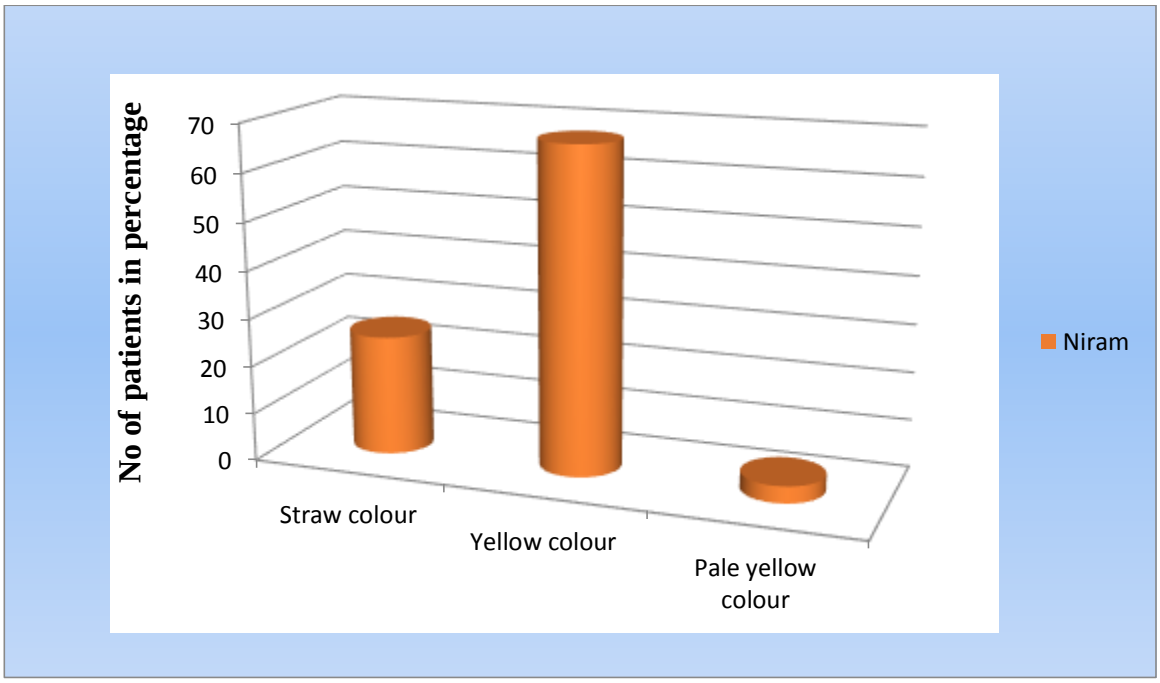


Inference:

Out of 40 patients 18 patients (45%) had Valiazhal naadi, 4 patients (10%) had ValiIyam naadi, 12 patients (30%) had Azhalvali naadi, 2 Patient (5%) had Azhaliyam naadi, 2 Patienst (5%) had Iyavatham naadi, 2 patients (5%) had Iyavali naadi.

13. NEERKKURI:

S.No.	Niram	No. ofCases	Percentage
1.	Straw colour	10	25
2.	Yellow colour	27	67.5
3.	Pale yellow colour	3	7.5

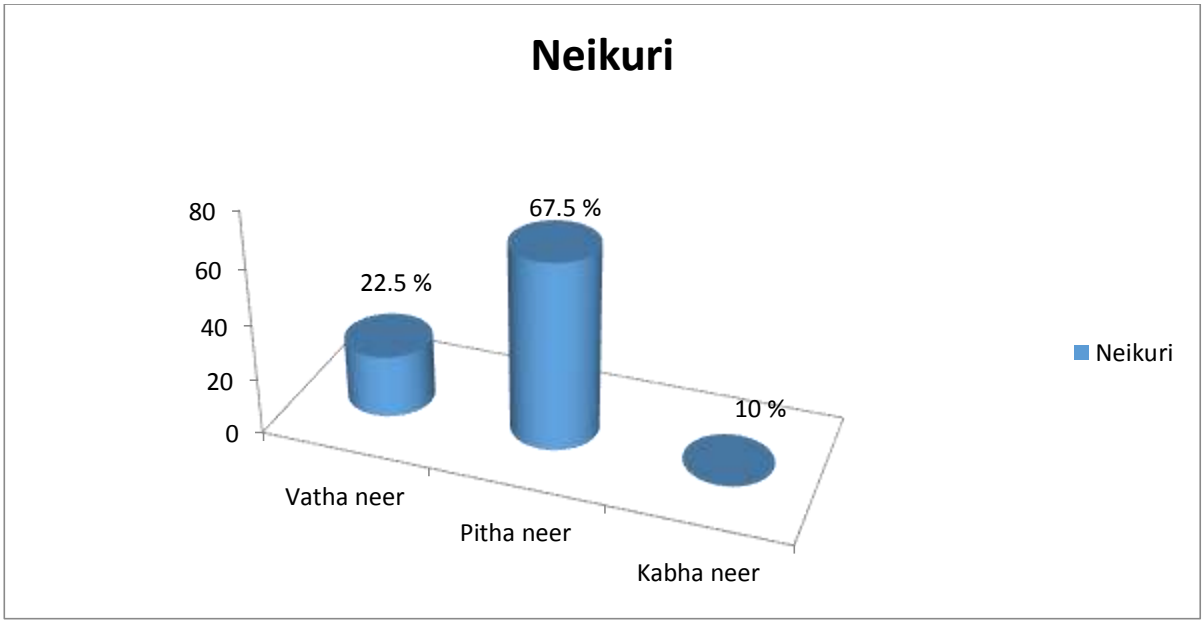


Inference:

Out of 40 cases, 10 (25%) of cases showed straw coloured urine, 27 (67.5%) of cases showed yellow coloured urine, 3 (7.5%) of cases showed Pale yellow coloured urine.

14. NEIKKURI

S. No	THATHU	NEIKURI	NUMBER OF CASES	PERCENTAGE (%)
1	Vathaneer	Spread like snake	9	22.5%
2	Pithaneer	Spread like Ring	27	67.5%
3	Kabhaneer	Spread like pearl	4	100%

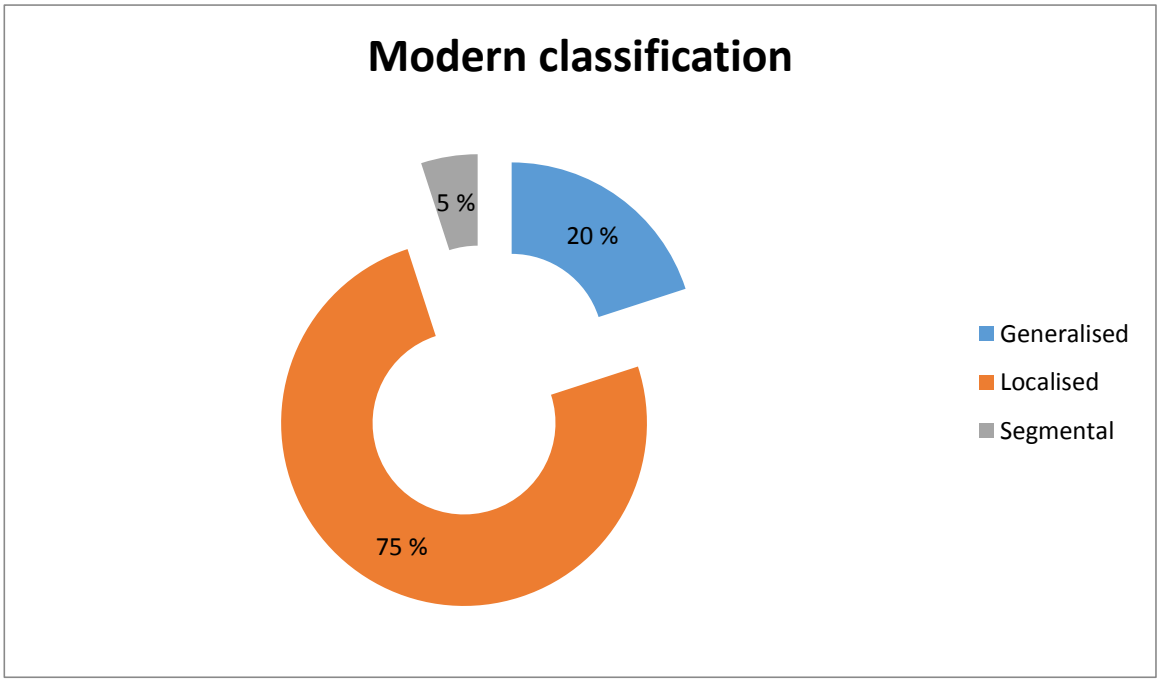


Inference:

Out of 40 cases 9 (22.5%) of patients showed Vatham type of neikkuri pattern, 27 (67.5) of patients showed Pitham type of neikkuri pattern and 4 (10%) of patients showed Kabam type of neikkuri pattern.

15. MODERNCLASSIFICATION:

S. No	Classification	No. of cases	Percentage
1.	Generalised	8	20
2.	Localised	30	75
3.	Segmental	2	5

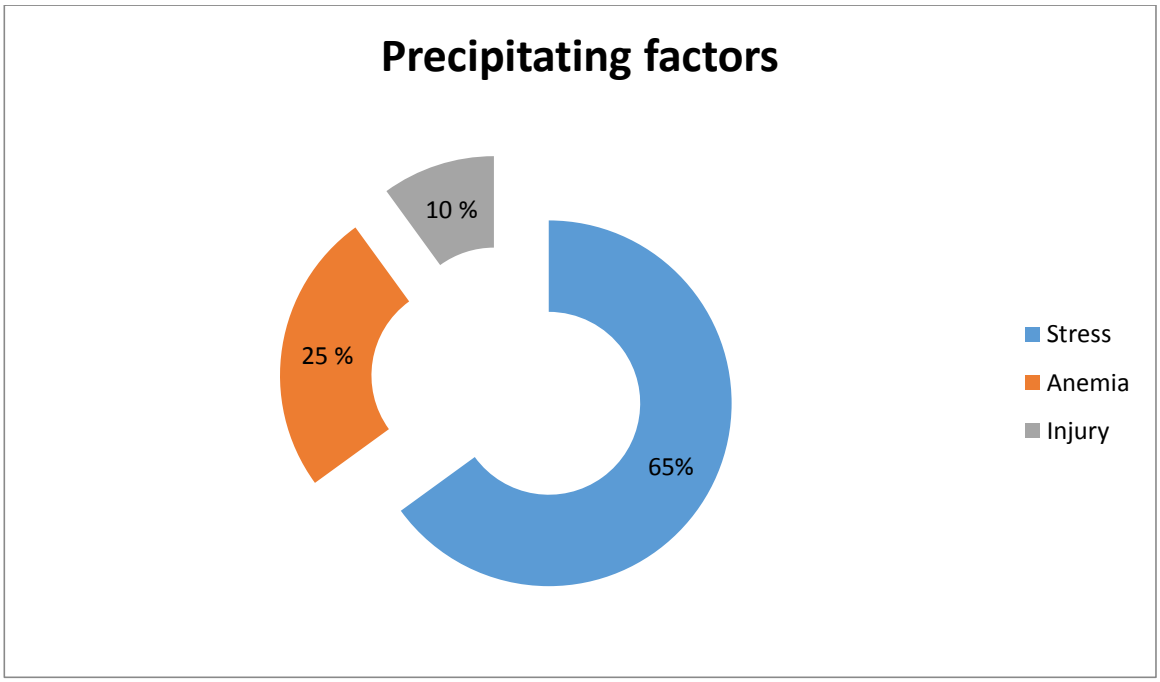


Inference:

Out of 40 cases Generalised vitiligo was seen in 8 (20%) cases, Localized vitiligo in 30 (75%) cases, Segmental Vitiligo in 2 (5%) cases.

16. PRECIPITATING FACTORS

S. No	PRECIPITATING FACTORS	No. of Cases	Percentage
1.	Stress	26	65
2.	Anemia	10	25
3.	Injury	4	10

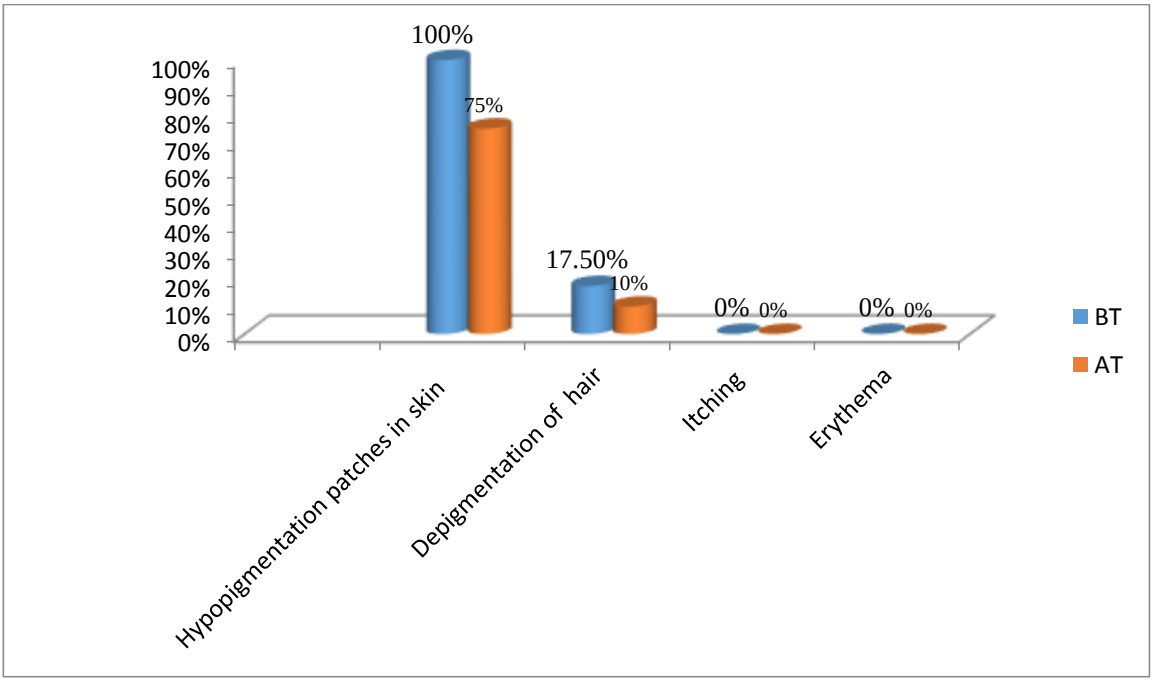


Inference:

Out of 40 cases, Stress precipitated Vitiligoin 26 (65%) cases, Anemia precipitated Vitiligo in 10 (25%) cases and Injury precipitated Vitiligo in 2 (10%) cases.

17. CLINICAL FEATURES

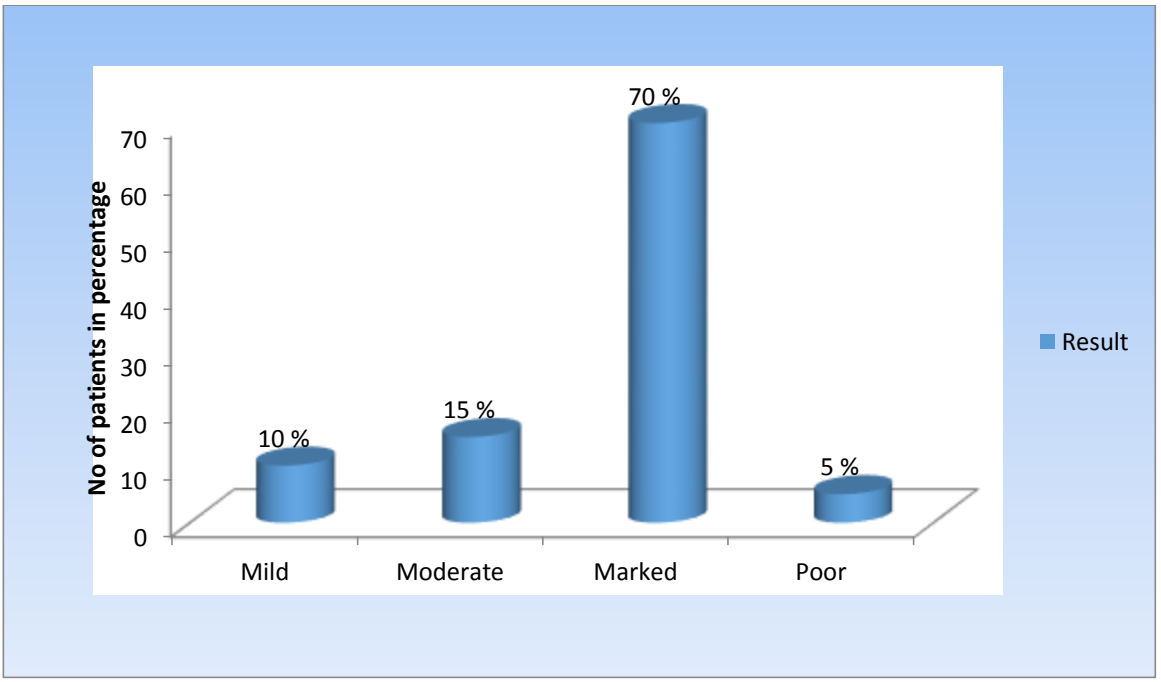
SIGN AND SYMPTOMS	BEFORE TREATMENT		AFTER TREATMENT	
	NO.OF CASES	PERCENTAGE (%)	NO.OF CASES	PERCENTAGES (%)
Hypopigmentation patches in skin	40	100%	30	75%
Depigmentation of hair	7	17.5 %	4	10%
Itching	0	0%	0	0%
Erythema	0	0%	0	0%



17. RESULTS

A. PATIENTS TREATED WITH BOTH TRAIL DRUGS (20 PATIENTS)

S. No	Result	No. of Cases	Percentage %
1	Mild	2	10
2	Moderate	3	15
3	Marked	14	70
4	Poor	1	5

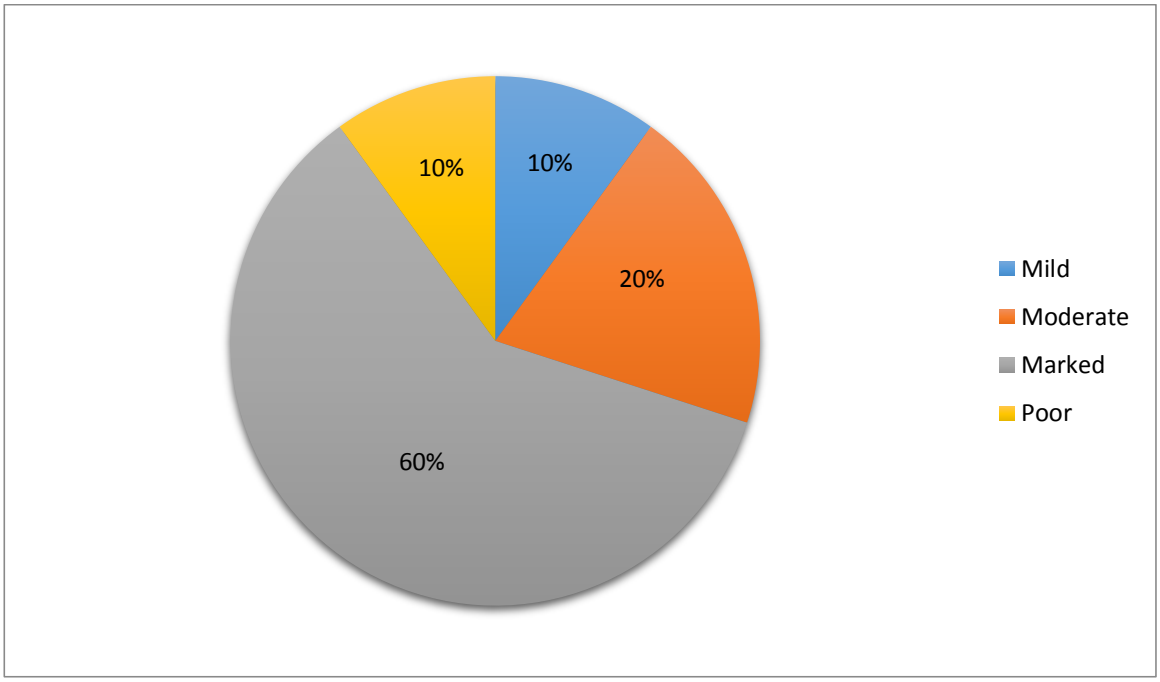


Inference:

Out of 20 patients treated with internal and external drug, 2 (10%) case showed mild improvement, 3 (15%) cases showed moderate improvement, 14 (70%) showed marked improvement, 1(5 %) case showed poor improvement.

B. PATIENTS TREATED WITH INTERNAL TRAIL DRUG (20 PATIENTS)

S. No	Result	No. of Cases	Percentage%
1	Mild	2	10
2	Moderate	4	20
3	Marked	12	60
4	poor	2	10



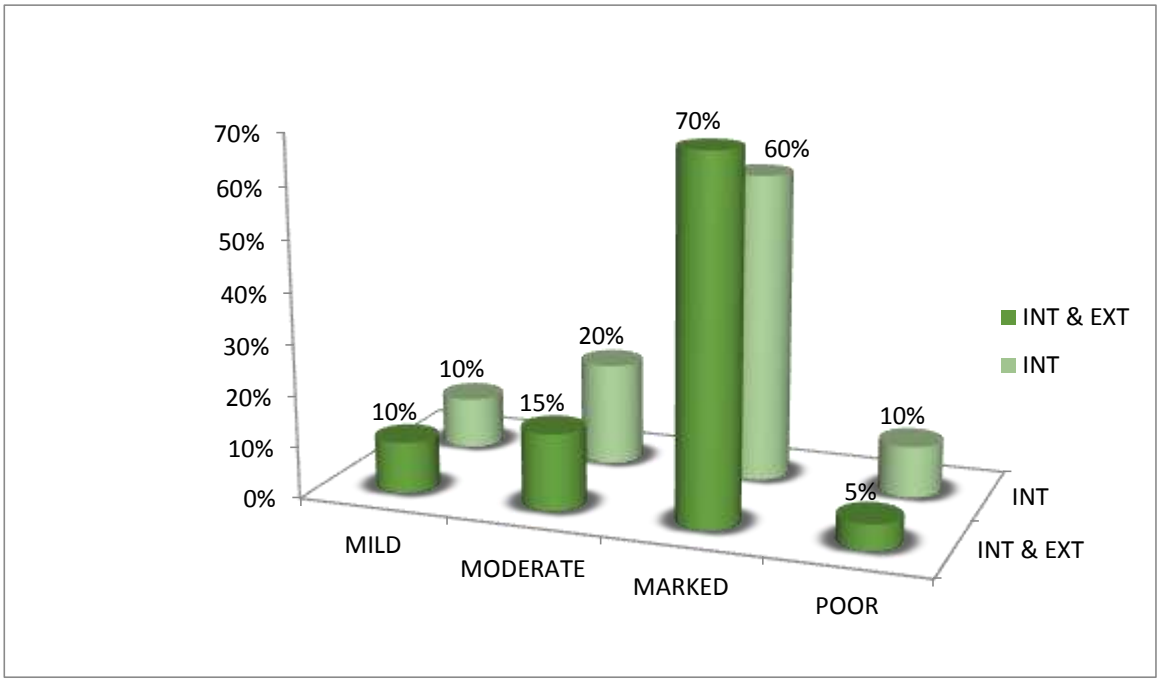
Inference:

20 patients treated with internal drug, which yield Mild Improvement in 2 [10%) cases, Moderate Improvement in 4 (20%) cases, Marked Improvement in 12 (60%) cases and poor improvement in 2(10%) cases were noted.

C.COMPARISION OF RESULTS:

PATIENTS TREATED WITH BOTH DRUGS (20 Pts) AND INTERNAL DRUG ALONE(20 Pts)

S.No	Results	Both Drug		Internal Drug only	
		No. ofCases	Percentage%	No. ofCases	Percentage%
1	Mild	2	10	2	10
2	Moderate	3	15	4	20
3	Marked	14	70	12	60
4	poor	1	5	2	10

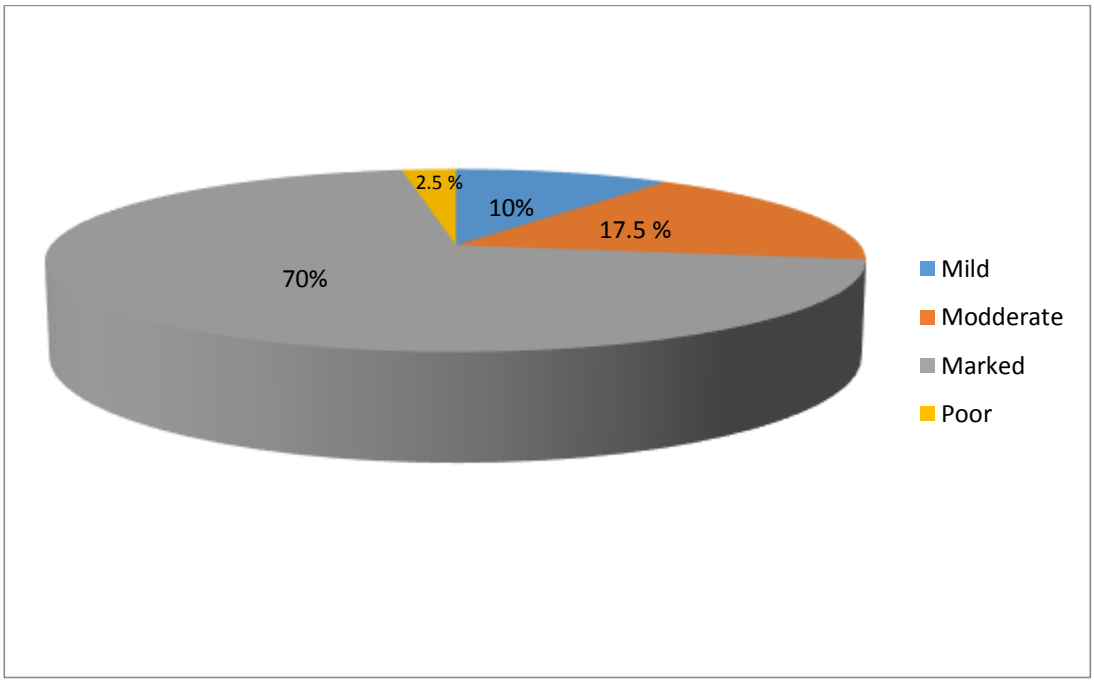


Inference:

The higher incidence is Marked improvement occurs in administration of both drugs (70%) than internal drug alone (60%).

D. RESULTS AFTER TREATMENT

S. No	Results	No. of Cases	Percentage
1.	Mild	4	10
2.	Moderate	7	17.5
3.	Marked	28	70
4.	Poor	1	2.5



Inference:

Out of 40 cases, 4 (10 %) of cases showed Mild improvement,7 (17.5%) of cases showed Moderate improvement, 28 (70 %)of cases showed Marked improvement and 1 (2.5%) of case showed Poor improvement.

OP NO : 5739

AGE /SEX: 24/ F

BEFORE TREATMENT

DURING TREATMENT

AFTER TREATMENT

OP.NO - 6020

AGE/SEX – 58/ M

BEFORE TREATMENT

DURING TREATMENT

AFTER TREATMENT

OP.NO – 2068 **AGE/SEX – 23/M**

BLOOD ANALYSIS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)** PALAGARAI KUZHAMBU (EXT)

	OP. NO	**AGE/ SEX**	**Hb (gm)**		**TC (cu.mm)**		**DC**						**ESR**				**Bl sugar**		**Urea**	**creatinine**	**urea**	**creatinine**
							N		**L**		**E**		**½ hr**	**1/2 hr**	**1hr**	**1hr**	**R**		**BT**	**BT**	**AT**	**AT**
			BT	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**				
1	5003	25/F	12.2	13	8200	8700	69	71	25	27	6	2	10	4	18	6	105	110	18	0.8	20	0.7
2	5117	52/M	14.4	14	9800	9600	57	59	38	38	5	3	18	8	40	12	106	98	22	0.4	18	0.6
3	5078	44 / M	13	14	9500	9900	60	64	34	33	6	3	24	4	50	10	110	120	30	0.6	20	0.7
4	5222	41 / F	13.2	13.5	8000	8500	58	61	35	34	7	6	10	4	18	6	100	96	20	0.5	14	0.5
5	5739	24 / F	13.2	13.4	8400	9700	52	57	40	38	8	5	5	2	12	4	80	90	18	0.4	24	0.6
6	6758	37 / F	11.2	12	10000	10400	46	49	48	48	6	3	22	4	38	6	112	116	22	0.4	27	0.6
7	6798	56 / F	12.8	13	7600	8900	49	55	41	39	10	6	14	2	20	4	102	94	17	0.6	24	0.8
8	6488	52 / M	12.5	13.5	9200	9300	56	62	41	36	3	2	16	4	34	6	118	100	19	0.7	19	0.7
9	2068	23 / M	13	14	8700	9400	62	68	32	29	4	3	12	4	32	10	85	112	14	0.6	29	0.6
10	3711	37 / M	12.6	13	8500	9700	55	61	40	36	5	3	8	2	16	4	94	88	30	0.6	22	0.8
11	4374	47 / M	13	13.5	9300	10000	65	69	31	29	4	2	16	8	32	6	103	106	34	0.6	24	0.7
12	2064	30 / F	10.8	12	7800	8900	62	68	33	30	5	2	6	2	12	6	113	120	16	1.1	23	0.8
13	3861	33 / F	9.6	11	10500	10700	53	60	40	37	7	3	4	2	10	4	87	98	21	0.5	20	0.9
14	6658	37 / F	11	11.5	9700	10000	64	70	33	27	3	2	20	12	40	22	97	114	23	0.6	19	0.6
15	7304	27 /M	13.5	14	8200	8500	54	58	39	37	7	5	10	2	34	4	111	86	14	0.5	14	0.7
16	4283	59 / F	12.8	13	8300	9000	59	66	34	30	7	4	30	4	62	10	98	112	28	0.3	16	0.5
17	4883	30 / F	10	11	9900	10300	63	70	31	27	6	3	32	2	52	6	110	90	22	0.5	28	0.5
18	6020	60 / M	14.1	14.5	5,500	7500	64	70	28	26	8	4	16	4	22	8	60	80	16	0.7	26	0.6
19	5188	50 / M	13	13.6	7900	8600	49	57	45	37	6	6	10	2	20	6	115	93	20	0.5	20	0.7
20	6784	34 / F	12.1	13	14400	14600	66	70	28	26	6	4	5	2	15	4	94	105	18	0.8	22	0.9

BLOOD ANALYSIS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)**

SI. No	**OP. NO**	**AGE/ SEX**	**Hb (gm)**		**TC (cu.mm)**		**DC**						**ESR**				**Bl sugar**		**urea**	**creatinine**	**Urea**	**creatinine**
							N		**L**		**E**		**½ hr**	½ hr	**1hr**	**1hr**	**R**					
			BT	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**BT**	**AT**	**AT**
21	6710	27 / M	14	14.5	9700	9900	52	57	42	40	6	3	26	14	50	12	98	120	14	0.8	20	0.7
22	6792	41 / F	11	12	6900	6700	58	60	37	35	5	5	16	4	32	10	92	110	24	0.7	32	0.9
23	9198	41 / F	9	10.5	8400	9000	41	45	41	50	8	5	10	8	6	2	110	89	20	0.5	20	0.6
24	7460	26 / M	13.5	14	8700	8600	42	50	51	45	7	5	22	6	12	4	96	88	23	0.6	29	0.6
25	2950	36 / F	13.6	14	8700	9200	45	55	35	42	10	3	10	6	8	2	75	90	16	0.7	14	0.7
26	3619	40 / F	11	12	7200	8000	47	50	44	45	9	5	10	8	20	4	114	98	15	0.7	23	0.6
27	613	43 / F	14.4	14.8	6600	7000	61	66	31	29	8	5	32	14	10	6	140	110	18	0.6	24	0.7
28	242	36 / M	12	13	8400	9000	53	55	42	42	5	3	12	2	36	4	118	104	14	0.9	13	0.8
29	241	32 / F	9	12	10000	10100	55	55	35	40	10	5	5	4	13	12	84	96	31	0.7	29	0.7
30	1297	22 / F	10.5	12.8	9800	10000	60	46	30	47	7	7	10	4	22	10	102	98	19	0.9	16	0.9
31	7229	60 / F	13	13	8900	9300	75	77	20	19	5	3	32	2	52	6	94	110	14	1.2	12	1.1
32	4304	47 / M	11	12	8000	8600	55	58	41	39	4	3	4	2	10	6	90	98	21	0.6	14	0.6
33	4305	35 / M	12.4	13.6	8400	8800	49	56	46	40	5	4	12	2	24	6	89	100	24	0.8	19	0.7
34	6006	22 / F	11	13	9100	9600	61	63	35	34	4	3	10	2	20	4	119	101	23	0.7	23	0.6
35	6004	40 / M	13	14.4	10300	10100	50	61	46	37	4	2	40	6	82	12	98	90	19	0.7	22	0.8
36	9321	57 / M	13.5	14	9600	9900	54	55	35	43	9	1	30	4	62	10	88	112	26	1.2	17	1.1
37	9423	19 / F	9.4	11	9000	9300	50	60	47	39	3	2	8	16	16	36	96	91	23	0.5	14	0.6
38	9503	40 / F	9.8	10.6	7800	8100	54	60	42	38	2	1	4	2	10	4	120	98	20	0.7	16	0.7
39	9521	18 / M	13	14.2	7600	7900	57	59	39	36	4	5	2	2	4	4	110	104	14	0.6	19	0.6
40	6003	21 / M	14	14.5	8500	8700	58	60	38	38	4	2	4	2	8	4	80	92	17	0.5	24	0.8

LIVER FUNCTION TESTS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)** AND PALAGARAI KUZHAMBU (EXT)

S.NO	OP.NO	AGE/SEX	BEFORE TREATMENT					AFTER TREATMENT				
			T.BILURUBIN mg / dl	D.BILURUBN mg / dl	ID.BILIRUBIN Mg / dl	SGOT IU / L	SGPT IU /L	T.BILIRUBIN mg / dl	D.bilirubin mg / dl	ID.BILIRUBIN mg/dl	SGOT IU / L	SGPT IU / L
1	5003	25/F	0.6	0.2	0.4	24	22	0.5	0.2	0.5	28	32
2	5117	52/M	0.8	0.3	0.6	13	20	0.5	0.3	0.3	12	10
3	5078	44 / M	0.7	0.2	0.4	22	26	0.8	0.3	0.3	10	16
4	5222	41 / F	0.8	0.3	0.4	14	37	0.6	0.2	0.4	17	19
5	5739	24 / F	0.7	0.2	0.5	26	20	0.6	0.3	0.3	18	21
6	6758	37 / F	0.5	0.2	0.5	16	27	0.4	0.3	0.4	16	12
7	6798	56 / F	0.7	0.3	0.3	24	16	0.8	0.3	0.5	22	18
8	6488	52 / M	0.6	0.3	0.3	14	20	0.7	0.2	0.5	14	19
9	2068	23 / M	0.4	0.2	0.2	11	15	0.5	0.2	0.5	16	10
10	3711	37 / M	0.7	0.3	0.5	22	18	1.1	0.4	0.4	12	17
11	4374	47 / M	0.5	0.3	0.2	21	22	0.5	0.3	0.7	20	14
12	2064	30 / F	0.4	0.3	0.3	17	19	0.6	0.3	0.8	21	22
13	3861	33 / F	0.7	0.2	0.4	16	20	0.9	0.2	0.2	19	21
14	6658	37 / F	0.8	0.3	0.5	32	18	0.8	0.2	0.5	20	18
15	7304	27 /M	0.7	0.2	0.2	15	24	1.2	0.4	0.3	10	17
16	4283	59 / F	0.6	0.3	0.5	24	20	0.7	0.2	0.2	14	23
17	4883	30 / F	0.5	0.3	0.6	15	54	0.5	0.2	0.4	19	14
18	6020	60 / M	0.8	0.2	0.5	25	18	0.7	0.3	0.5	44	27
19	5188	50 / M	0.7	0.2	0.6	21	32	0.5	0.3	0.3	10	17
20	6784	34 / F	0.7	0.2	0.4	18	16	0.7	0.6	0.5	12	18

LIVER FUNCTION TESTS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT**)

S.NO	OP.NO	AGE/SEX	BEFORE TREATMENT					AFTER TREATMENT				
			T.BILURUBIN mg / dl	D.BILURUBN mg / dl	ID.BILIRUBIN Mg / dl	SGOT IU / L	SGPT IU /L	T.BILIRUBIN mg / dl	D.bilirubin mg / dl	ID.BILIRUBIN mg/dl	SGOT IU / L	SGPT IU / L
21	6710	27 / M	0.8	0.3	0.5	12	13	0.5	0.2	0.5	26	24
22	6792	41 / F	1.2	0.4	0.5	13	24	0.6	0.3	0.6	17	12
23	9198	41 / F	0.9	0.3	0.4	26	21	0.8	0.2	0.3	32	34
24	7460	26 / M	0.8	0.2	0.6	19	15	0.7	0.2	0.4	10	12
25	2950	36 / F	1.50	0.3	1.29	18.5	18	0.4	0.2	0.3	19	12
26	3619	40 / F	0.6	0.3	0.2	13	19	1.3	0.3	0.4	21	24
27	613	43 / F	0.7	0.3	0.3	16	25	0.8	0.3	0.6	10	17
28	242	36 / M	0.8	0.2	0.3	23	63	0.6	0.2	0.5	32	40
29	241	32 / F	0.4	0.3	0.4	37	23	0.9	0.3	0.5	18	20
30	1297	22 / F	0.7	0.3	0.4	19	24	0.6	0.3	0.5	16	24
31	7229	60 / F	0.8	0.2	0.3	15	19	0.8	0.2	0.4	16	20
32	4304	47 / M	0.8	0.2	0.5	22	18	0.4	0.4	0.5	28	24
33	4305	35 / M	0.6	0.2	0.3	17	16	0.7	0.3	0.4	17	22
34	6006	22 / F	0.4	0.3	0.2	13	15	0.9	0.2	0.4	23	28
35	6004	40 / M	0.9	0.3	0.5	27	33	0.6	0.3	0.2	15	11
36	9321	57 / M	1.0	0.3	0.5	17	13	0.5	0.2	0.3	27	19
37	9423	19 / F	0.5	0.2	0.3	32	31	0.8	0.4	0.2	18	22
38	9503	40 / F	0.4	0.2	0.3	14	17	0.8	0.4	0.5	28	24
39	9521	18 / M	0.8	0.3	0.6	23	26	0.9	0.3	0.3	16	28
40	6003	21 / M	0.6	0.3	0.5	22	17	0.7	0.2	0.4	12	19

VASI SCORE FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT) PALAGARAI KUZHAMBU (EXT)**

S. NO	OP. NO	HEAD				UPPER LIMB				TRUNK				LOWER LIMB				TOTAL SCORE	
		D_H		A_H		D_H		A_H		D_T		A_T		D_L		A_L			
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	5003	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0.1	0.1
2	5117	2	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0.4	0.1
3	5078	2	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0
4	5222	3	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0.1
5	5739	0	0	0	0	3	1	5	3	0	0	0	0	0	0	0	0	3	0.6
6	6758	0	0	0	0	2	1	4	2	0	0	0	0	0	0	0	0	1.6	0.4
7	6798	0	0	0	0	2	1	2	1	0	0	0	0	0	0	0	0	0.8	0.2
8	6488	0	0	0	0	2	1	2	1	0	0	0	0	0	0	0	0	0.8	0.2
9	2068	0	0	0	0	2	1	2	1	0	0	0	0	0	0	0	0	0.8	0.2
10	3711	0	0	0	0	2	1	2	1	0	0	0	0	0	0	0	0	0.8	0.1
11	4374	0	0	0	0	3	2	2	1	0	0	0	0	0	0	0	0	1.2	0.4
12	2064	0	0	0	0	0	0	0	0	2	0	4	0	0	0	0	0	2.4	0
13	3861	0	0	0	0	0	0	0	0	2	1	3	1	0	0	0	0	1.8	0.3
14	6658	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0.3	0.3
15	7304	0	0	0	0	0	0	0	0	0	0	0	0	3	0	1	0	1.2	0
16	4283	0	0	0	0	0	0	0	0	0	0	0	0	3	1	3	2	3.6	0.8
17	4883	0	0	0	0	0	0	0	0	0	0	0	0	2	1	2	1	1.6	0.4
18	6020	0	0	0	0	0	0	0	0	0	0	0	0	2	1	2	1	1.6	0.4
19	5188	0	0	0	0	0	0	0	0	0	0	0	0	3	2	2	1	2.4	0.8
20	6784	0	0	0	0	0	0	0	0	0	0	0	0	2	1	3	2	2.4	0.8

VASI SCORE FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)**

S. NO	OP. NO	HEAD				UPPER LIMB				TRUNK				LOWER LIMB				TOTAL SCORE	
		D_H		A_H		D_H		A_H		D_T		A_T		D_L		A_L		BT	AT
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT		
21	6710	0	0	0	0	3	1	5	3	0	0	0	0	0	0	0	0	3	0.6
22	6792	0	0	0	0	2	1	4	2	0	0	0	0	0	0	0	0	1.6	0.4
23	9198	0	0	0	0	3	2	2	1	0	0	0	0	0	0	0	0	1.2	0.4
24	7460	0	0	0	0	0	0	0	0	2	0	4	0	0	0	0	0	2.4	0
25	2950	2	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0.4	0.1
26	3619	2	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0
27	613	3	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0.1
28	242	0	0	0	0	0	0	0	0	0	0	0	0	2	1	2	1	1.6	0.4
29	241	0	0	0	0	0	0	0	0	0	0	0	0	3	2	2	1	2.4	0.8
30	1297	0	0	0	0	0	0	0	0	2	1	3	1	0	0	0	0	1.8	0.3
31	7229	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0.3	0.3
32	4304	0	0	0	0	0	0	0	0	0	0	0	0	3	0	1	0	1.2	0
33	4305	0	0	0	0	2	1	2	1	0	0	0	0	0	0	0	0	0.8	0.2
34	6006	0	0	0	0	2	1	2	1	0	0	0	0	0	0	0	0	0.8	0.1
35	6004	0	0	0	0	0	0	0	0	0	0	0	0	3	1	3	2	3.6	0.8
36	9321	0	0	0	0	0	0	0	0	0	0	0	0	2	1	2	1	1.6	0.4
37	9423	2	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0.4	0.1
38	9503	2	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0.6	0
39	9521	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0.3	0.3
40	6003	0	0	0	0	0	0	0	0	0	0	0	0	3	0	1	0	1.2	0

URINE ANALYSIS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT) AND PALAGARAI KUZHAMBU (EXT)**

S.NO	OP.NO	AGE/SEX	BEFORE TREATMENT				**AFTER TREATMENT**			
			ALBUMIN	SUGAR	DEPOSITS		ALBUMIN	SUGAR	DEPOSITS	
					EPITHELIAL CELLS	PUS CELLS			EPITHELIAL CELLS	PUS CELLS
1	5003	25/F	NIL	NIL	1-2	2-4	NIL	NIL	1-2	1-2
2	5117	52/M	NIL	NIL	3 -4	1-4	NIL	NIL	2-4	1-2
3	5078	44 / M	NIL	NIL	2-5	2-4	NIL	NIL	1-2	1-2
4	5222	41 / F	NIL	NIL	2-4	1-2	NIL	NIL	1-2	2-3
5	5739	24 / F	NIL	NIL	1-5	NIL	NIL	NIL	2-3	1-2
6	6758	37 / F	NIL	NIL	2-4	2-4	NIL	NIL	1-2	1-2
7	6798	56 / F	NIL	NIL	2-4	2-3	NIL	NIL	2-3	2-3
8	6488	52 / M	NIL	NIL	2-3	3-6	NIL	NIL	1-2	4-5
9	2068	23 / M	NIL	NIL	2-4	2-4	NIL	NIL	2-3	1-2
10	3711	37 / M	NIL	NIL	2-4	1-2	NIL	NIL	1-2	1-2
11	4374	47 / M	NIL	NIL	1-3	2-4	NIL	NIL	1-2	1-2
12	2064	30 / F	NIL	NIL	3-5	2-3	NIL	NIL	2-4	4-5
13	3861	33 / F	NIL	NIL	4-6	6-8	NIL	NIL	2-4	1-2
14	6658	37 / F	NIL	NIL	2-4	2-4	NIL	NIL	1-2	2-3
15	7304	27 /M	NIL	NIL	1-2	1-2	NIL	NIL	2-4	1-2
16	4283	59 / F	NIL	NIL	2-4	1-3	NIL	NIL	2-4	1-2
17	4883	30 / F	NIL	NIL	2-3	1-3	NIL	NIL	1-2	1-2
18	6020	60 / M	NIL	NIL	3-5	2-4	NIL	NIL	2-4	3-5
19	5188	50 / M	NIL	NIL	2-4	1-3	NIL	NIL	1-2	1-3
20	6784	34 / F	NIL	NIL	2-4	3-5	NIL	NIL	1-2	1-3

URINE ANALYSIS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)**

S.NO	OP.NO	AGE/SEX	BEFORE TREATMENT				**AFTER TREATMENT**			
			ALBUMIN	SUGAR	DEPOSITS		ALBUMIN	SUGAR	DEPOSITS	
					EPITHELIAL CELLS	PUS CELLS			EPITHELIAL CELLS	PUS CELLS
21	6710	27 / M	NIL	NIL	2-5	2-4	NIL	NIL	2-4	1-2
22	6792	41 / F	NIL	NIL	4-6	2-4	NIL	NIL	2-3	1-3
23	9198	41 / F	NIL	NIL	6-8	3-6	NIL	NIL	2-3	1-2
24	7460	26 / M	NIL	NIL	1-2	2-4	NIL	NIL	1-2	1-3
25	2950	36 / F	NIL	NIL	1 – 3	2-3	NIL	NIL	1-3	1-3
26	3619	40 / F	NIL	NIL	1-2	2-4	NIL	NIL	2-4	1-4
27	613	43 / F	NIL	NIL	1-2	1-2	NIL	NIL	1-2	1-2
28	242	36 / M	NIL	NIL	2-4	2-4	NIL	NIL	1-2	1-3
29	241	32 / F	NIL	NIL	2-4	2-3	NIL	NIL	2-4	1-2
30	1297	22 / F	NIL	NIL	2-6	2-4	NIL	NIL	1-4	1-4
31	7229	60 / F	NIL	NIL	1-2	1-3	NIL	NIL	1-2	1-4
32	4304	47 / M	NIL	NIL	4-6	2-4	NIL	NIL	2-4	1-3
33	4305	35 / M	NIL	NIL	6-8	2-3	NIL	NIL	2-4	1-5
34	6006	22 / F	NIL	NIL	3-5	1-2	NIL	NIL	1-2	3-5
35	6004	40 / M	NIL	NIL	1-2	1-2	NIL	NIL	1-2	1-3
36	9321	57 / M	NIL	NIL	2-4	3-6	NIL	NIL	2-4	2-3
37	9423	19 / F	NIL	NIL	2-4	2-4	NIL	NIL	1-2	3-5
38	9503	40 / F	NIL	NIL	2-3	2-3	NIL	NIL	1-2	1-2
39	9521	18 / M	NIL	NIL	1-3	2-4	NIL	NIL	1-3	1-2
40	6003	21 / M	NIL	NIL	1-2	1-2	NIL	NIL	2-4	1-2

CLINICAL PROGNOSIS

LIVER FUNCTION TESTS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT**) AND PALAGARAIKUZHAMBU (EXT)

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
2	SGPT	23.20±9.07	18.25±5.32	**0.065**
3	SGOT	19.50±5.40	17.70±7.78	**0.309**
4	Total bilirubin	0.64±0.12	0.68±0.20	**0.433**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

LIVER FUNCTION TESTS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT**)

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
2	SGPT	22.50±11.02	21.80±7.36	**0.763**
3	SGOT	19.92±6.70	20.05±6.78	**0.955**
4	Total bilirubin	0.76±0.27	0.71±0.20	**0.643**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

RFT FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT**) PALAGARAIKUZHAMBU (EXT)

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
1	Urea	21.10±5.54	21.45±4.27	**0.833**
2	Creatinine	0.58±0.17	0.67±0.12	**<0.05**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

RFT FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)**

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
1	Urea	19.75±4.67	20.00±5.73	**0.843**
2	Creatinine	0.73±0.19	0.74±0.15	**0.694**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

BLOOD ANALYSIS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT**) PALAGARAIKUZHAMBU (EXT)

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
1	Hb	12.49±1.27	13.02±1.01	**<0.001**
2	ESR1hr	28.85±14.87	7.20±4.22	**<0.001**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

BLOOD ANALYSIS FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)**

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
1	Hb	11.90±1.77	12.99±1.34	**<0.001**
2	ESR1 hr	24.85±21.33	7.90±7.41	**<0.05**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

VASI SCORE FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT) PALAGARAI KUZHAMBU (EXT)**

S.No.	BT VASI Score	AT VASI Score
1	0.1	0.1
2	0.4	0.1
3	0.6	0
4	0.6	0.1
5	3	0.6
6	1.6	0.4
7	0.8	0.2
8	0.8	0.2
9	0.8	0.2
10	0.8	0.1
11	1.2	0.4
12	2.4	0
13	1.8	0.3

14	0.3	0.3
15	1.2	0
16	3.6	0.8
17	1.6	0.4
18	1.6	0.4
19	2.4	0.8
20	2.4	0.8

Software: spss17 version

Variables: VASI Score – before treatment, after treatment

Number of cases: 20

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.734

Before and after treatment mean difference: 1.09 ± 0.78.

P Value (2 tailed): p<0.001.

Inference:

Since the P value is highly significant (<0.001). So there is significant reducing of VASI Score among the patients for the treatment of Venpulli (Vitiligo). Hence it is concluded that the treatment was effective and **significant.**

VASI SCORE FOR OPD PATIENTS TREATED WITH INTERNAL MEDICINE **RASA CHENDHURAM (INT)**

S.No.	**BT VASI Score**	**AT VASI Score**
1	3	0.6
2	1.6	0.4
3	1.2	0.4
4	2.4	0
5	0.4	0.1
6	0.6	0
7	0.6	0.1
8	1.6	0.4
9	2.4	0.8

10	1.8	0.3
11	0.3	0.3
12	1.2	0
13	0.8	0.2
14	0.8	0.1
15	3.6	0.8
16	1.6	0.4
17	0.4	0.1
18	0.6	0
19	0.3	0.3
20	1.2	0

Software: spss17 version

Variables: VASI Score – before treatment, after treatment

Number of cases: 20

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.685

Before and after treatment mean difference: 1.05 ± 0.78.

P Value (2 tailed): $p<0.001$.

Inference:

Since the P value is highly significant (<0.001). So there is significant reducing of VASI Score among the patients for the treatment of Venpulli (Vitiligo). Hence it is concluded that the treatment was effective and **significant.**

DISCUSSION

Skin disease is often easily noticeable than other disease. Appearance of the skin can determine the status of each individual incarnation of himself .Due to changes in a person's appearance, venpulli (vitiligo) patients often experience psychological stress and suffer from social stigma.

Yugi vaithiya chinthamani mention venpulli noi as swetha kuttam which comes under the eighteen types of kuttam. As the term kuttam bears social stigma, the disease is called as venpulli.

The clinical entity of venpulli noi is more or less similar to that of vitiligo in modern medicine. Vitiligo is an acquired, idiopathic, depigmentory condition of skin and hair varying sizes and shapes. It is varying sizes and shapes. Besides loss of colour there is no other structural change.

The author has collected information largely from various siddha and modern textbook. 40 patients were selected from Govt Siddha Medical College OPD on both siddha and modern diagnostic method under the investigation of my guide.

The trial drugs for this study were prepared by the Author in the Gunapadam practical lab, Govt Siddha Medical College, under the supervision of the members of the teaching faculty and guided by the Head of the Department of Sirappu Maruthuvam, Govt Siddha Medical College, Arumbakkam, Chennai -106. The trial drugs Rasa Chenduram (Internal) and palagarai kuzhambu (External**)** were given for 48 days. Out-Patients were asked to visit the hospital once in 7 days. For Out-Patients the drugs were given for 48 days and the clinical assessment was done on 0^{th}day, 8^{th} day, 15^{th} day, 22^{th} day 29^{th} day, 36th day, 43rdday, 48thday.

Patients were instructed to take the medicines regularly and apply the external medicine twice a day and to expose the affected parts to sunlight in the morning. It was ensured that the diet restrictions such as non citric acid foods. imposed were followed properly by the patients. Before and after the course of treatment, the patients were subjected to laboratory investigations and photographs were taken.

Based on various criterias, the datas were collected and tabulate

DISTRIBUTION ACCORDING TO AGE :

- Out of 40 cases, 4 (10%) of cases belonged to the age group of 18-20 years.
- 9 (22.5%) of cases belonged to the age group of 21-30 years.
- 12 (30%) of cases belonged to the age group of 31-40 years
- 11 (27.5%) of cases belonged to the age group of 41-50 years
- 7 (17.5%) of cases belonged to the age group of 51-60 years.

DISTRIBUTION ACCORDING TO GENDER:

- 18(45%) were Male,
- 22 (55%) cases were Female.

DISTRIBUTION ACCORDING TO DIETARY HABITS :

- Out of 40 cases 7(17.5%) of cases were Vegetarians
- 33 (82.5 %) cases were Non- vegetarians.

DISTRIBUTION ACCORDING TO OCCUPATION :

- 8 (20 %) were Student
- 15 (37.5%) were Home maker,
- 9 (22.5%) were Office Workers
- 4 (10%) were businessmen
- 4 (10%) were others

DISTRIBUTION ACCORDING TO SOCIO – ECONOMIC STATUS

- 67.5% comes under low economic status
- 22.5% of them under moderate status
- 10 % of them under high income status.

DISTRIBUTION ACCORDING TO FAMILY HISTORY :

- 36 (90%) of cases have no family history.
- 4 (10 %) of cases have family history

DISTRIBUTION ACCORDING TO THINAI:

- 36 (90%) from Neithal thinai.
- 4 (10%) of cases from Marutham thinai,

DISTRIBUTION ACCORDING TO PARUVAKAALAM

- 5 patients (12.5 %) were recorded in Karkaalam,
- 8 patients (20%) were recorded in Koothir Kaalam,
- 11 patients (27.5%) were recorded in Munpani Kaalam,
- 6 patients (15%) were recorded in Pinpani Kaalam,
- 3 patients (7.5 %) were recorded in Elavenil Kaalam
- 7 patients (17.5%) were recorded in Mudhuvenil Kaalam

DISTRIBUTION ACCORDING TO EZHU UDAL KATTUGAL

- Saaram was affected in all the 40 cases (100%)
- Senneer was affected in 40 cases (75%)
- oon was affected in 15 cases
- kozhuppu in was affected 15 cases (37.5)

DISTRIBUTION ACCORDING TO MUKKUTRAM

A. Vatham:

- Abanan was affected in 18 (45%) of cases.
- Viyanan was affected in 15 (37.5%) of cases
- Samanan was affected in 40(100%) of cases

B. Pitham:

- Ranjagam was affected in 20 of cases (50%)
- Prasagam was affected in all the 40 (100%) of cases.

C. Kabam

- Avalambagam was affected in 15 patients (37.5%)
- Santhigam was affected in 15 patients (37.5%).

DISTRIBUTION ACCORDING TO EN VAGAI THERVUGAL

- naa was affected in 12 cases (30 %)
- niram was affected in all the 40 (100 %) cases
- Malam was affected in 15 (37.5%) cases.

DISTRIBUTION ACCORDING TO NAADI

- 18 patients (45%) had Valiazhal naadi
- 4 patients (10%) had ValiIyam naadi,
- 12 patients (30%) had Azhalvali naadi
- 2 Patient (5%) had Azhaliyam naadi,
- 2 Patienst (5%) had Iyavathamnaadi
- 2 patients (5%) had Iyavalinaadi .

DISTRIBUTION ACCORDING TO NEERKKURI:

- 10 (25%) of cases showed straw coloured urine
- 27 (67.5%) of cases showed yellow coloured urine
- 3 (7.5%) of cases showed Pale yellow coloured urine.

DISTRIBUTION ACCORDING TO NEIKKURI :

- 9 (22.5%) of patients showed Vatham type of neikkuri pattern
- 27 (67.5) of patients showed Pitham type of neikkuri pattern
- 4 (10%) of patients showed Kabam type of neikkuri pattern. **.**

DISTRIBUTION ACCORDING TO PRECIPITATING FACTORS :

- Stress precipitated Vitiligo in 26 (65%) cases
- Anemia precipitated Vitiligo in 10 (25%) cases
- Injury precipitated Vitiligo in 2 (10%) cases.

RESULTS

A.PATIENTS TREATED WITH BOTH TRAIL DRUGS (20 PATIENTS)

- 2 (10%) case showed mild improvement
- 3 (15%) cases showed moderate improvement
- 14 (70%) showed marked improvement
- 1 (5 %) case showed poor improvement

B. PATIENTS TREATED WITH INTERNAL TRAIL DRUG (20 PATIENTS)

- Mild Improvement in 2 (10%) cases
- Moderate Improvement in 4 (20%) cases
- Marked Improvement in 12 (60%) cases
- Poor improvement in 2(10%) cases

C.COMPARISION OF RESULTS

PATIENTS TREATED WITH BOTH DRUG (20 Pts) AND INTERNAL DRUG ALONE (20 Pts)

Marked improvement occurs in administration of both drugs (70%) than internal drug alone (60%).

Statistics Report :

Since the P value is highly significant (<0.001). So there is significant reducing of VASI Score among the patients for the treatment of Venpulli (Vitiligo). Hence it is concluded that the treatment was effective and significant.

P value for LFT & RFT is significant value. Hence the drug proves to be effective and significant.

SUMMARY

AN OPEN COMPARATIVE CLINICAL EVALUATION ON VENPULLI (VITILIGO) WITH SIDDHA TRIAL DRUGS "RASA CHENDHURAM" (INTERNAL) AND "PALAGARAI KUZHAMBU" (EXTERNAL) has been choosen for the dissertation work by the author

- The aim of the study was to evaluate the safety and and efficacy of siddha drug rasa chendhuram (internal) and palagarai kuzhambu (external) in the management of venpulli (vitiligo).
- Various Literature evidences have been collected from siddha and modern text books and also the drug review also said.
- Standared operative procedure for both trial drugs was standardized.
- Pre - clinical toxicity study was done for the trial drug rasa chendhuram in using of Wister albino rats. Toxicity study was carried out after getting proper permission in Institutional Animal Ethical Committee (IAEC).
- The study is conducted after the drug being screened by the screening committee and the trial is also approved by the Institutional Ethical Committee (IEC). The clinical trial also registered in Clinical Trial Registry Of India(CTRI)
- Qualitative and Quantitative study on the trial drug such as Physico-chemical analysis had been done, result sare normal in range.
- 40 Patients of both gender and in age group between 18-60 years were selected for this clinical trial.
- All the details about this study and the trial Drug rasa chendhuram consent forms duly signed by them, separate proforma was maintained for each patients.
- Before starting the treatment, the blood samples of the selected patients were subjected to investigation and photographs of the lesions were taken.
- From the first day onwards RASA CHENDHURAM , 65 mg twice daily was given internally with honey and PALAGARAI KUZHAMBU for external application given to the patients.
- Diet restrictions were strictly imposed during the treatment period especially foods rich in Vit-c should be avoided.

- The patients were assessed for clinical improvement and adverse effects during every visit.
- Before starting the treatment and at the end of the treatment the laboratory investigations were repeated.
- The photographs of the lesions were taken whenever necessary. Photographs were also taken before and after the trial. The improvement was assessed by change in colour of the lesion, repigmentation and reduction in size of the lesion.

CONCLUSION

The clinical study reveals the trial drugs showed marked improvement in 65% of cases, Moderate improvement in 17.5% of cases, Mild improvement in 10 % of cases, and Poor improvement in 7.5% of case.

A toxicological study in animal models reveals the safety and efficacy of the trial drug Rasa chenduram.

Clinically, no adverse effects were reported during the trial and the laboratory investigations were also within normal limit. So, the drug is assumed to be safe for humans.

Hereby I conclude my study by reveals the effectiveness of the trial drugs "Rasa Chendhuram - internal" and "Palagarai kuzhambu - external" are effective in producing repigmentation and reducing the size of the hypopigmented patches in the skin and hair "Venpulli noi" (Vitiligo).

GOVERNMENT SIDDHA MEDICAL COLLEGE
Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-4/2015/014

Protocol title: AN OPEN COMPARATIVE CLINICAL EVALUATION ON VENPULLI (VITILIGO) WITH SIDDHA TRIAL DRUGS "RASA CHENDHURAM" (INTERNAL) AND "PALAGARAI KUZHAMBU" (EXTERNAL).
Principal Investigator : Dr. R. Kalaimani
Name & Address of Institution: Government Siddha Medical College, Arumbakkam, Chennai-106
☑ New Review ☐ Revised Review ☐ Expedited Review
Date of review (DD/MM/YY): 26/03/2015 Date Of Previous Review, If Revised Application:
Decision of the IEC ☑ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions / Reasons / Remarks: Heavy metals analysis should be done.If metals level are raised from normal ppm level, chronic toxicity study should be done. Hypo pigmentation due to worm infestation should be removed from inclusion criteria.Patients having hypo pigmented patches in muco-cutaneous junction should be excluded.
Recommended for a period of 1 year from date of completion of preclinical studies :

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

20/3/15

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date:

Sub: IEC review of research proposals.

Ref: Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
DR.P.JEYAPRAKASH NARAYANAN M.D(S)., Chairman	✓	
DR.V.BANUMATHI M.D(S)., Member Secretary		
DR.N.KABILAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.P.SATHIYA RAJESWARAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.G.AADINAAATH REDDY,M.Pharm, Ph.D., Pharmacologist	✓	26/03/15
DR.S.THILAGAVATHY Msc.,Ph.D., Social Scientist	✓	26/3/15
DR.T.MAHALAKSHMI M.A.,Ph.D., Linguistic Expert	✓	
DR.P.VIDYA M.B.B.S., DMRD., Modern Medicine Expert	✓	26/3/15
MR.P.SARAVANAN., Public Person	✓	

26/3/15.

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

POONGA BIOTECH RESEARCH CENTRE

No.10/58, Kamala Nehru Nagar, 1st Street, Choolaimedu, Chennai - 600 094.
Ph : 044 - 23634289, Website : www.poongabiotech.com

Dr. B. Janarthanam
Chief Scientist,

12.07.2016

To whomsoever it may concern

This is to certify that Dr. R. Kalaimani, PG Scholar, Department of Sirappu Maruthuvam, Goverment Siddha Medical College, Arumbakkam, Chennai – 600 106 has carried out the following work in our centre.

1. Qualitative analysis of Heavy metal in Rosa Chenduram

B. Janarthanam

Dr. B. Janarthanam

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், சென்னை - 600 106
सिद्ध केंद्रीय अनुसन्धान संस्थान,
अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई – 600 106
SIDDHA CENTRAL RESEARCH INSTITUTE
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai – 600106
Phone: 044-2621 4925, Fax: 044-2621 4809

08.3.2017

CERTIFICATE

Name of the student: Dr. R. Kalaimani, III year PG student, Sirappu Maruthuvam, Government Siddha Medical College, Arumbakkam, Chennai-600 106.

Name of the sample: Rasa Chendhooram

Name of the Experiment	Value
Loss on drying(at 105°C)	0 %
Total ash	91.5 %
Water soluble ash	29.0 %
Acid insoluble ash	48 %
pH value (10%)	1.47

(R. Shakila)
Research Officer (Chemistry) & Head,
Department of Chemistry

(Dr. P. Sathiyarajeswaran)
Assistant Director (Siddha) I/c

C.L.BAID METHA COLLEGE OF PHARMACY

(An ISO 9001-2000 certified institute)

Jyothi Nagar, Old Mahabalipuram Road

Thoraipakkam, Chennai – 600 097

CERTIFICATE

This is to certify that the project entitled, **Toxicological and Pharmacological study on RASA CHENDHURAM** in rats submitted in partial fulfilment for the degree of **M.D. (siddha)** was carried out at C.L. Baid Metha college of Pharmacy, Chennai-97, in the Department of Pharmacology during the academic year of 2015-2016. It has been approved by the

IAEC No: IAEC/XLVIII/30/CLBMCP/2016

C.L. Baid Metha College of Pharmacy CHENNAI-97 Thoraipakkam

(Dr.P.Muralidharan)

IAEC Member Secretary

The Tamil Nadu Dr.M.G.R. Medical University

#69, Anna salai, Guindy, Chennai-600 032.

This certificate is awarded to

Dr./Mr./Ms. R. KALAI MANI

for participating as ~~Resource Person~~ / Delegate in the First Workshop on

"Pre-clinical Studies in Research"

for Faculties & PG students of ASU Systems

Organised by the Department of Siddha,

The Tamil Nadu Dr. M.G.R. Medical University on 16.12.2014

Dr. N. KABILAN M.D. (Siddha)
Reader, Dept. of Siddha

Dr. JHANSI CHARLES, M.D.
Registrar

Prof. Dr. D. SHANTHARAM, M.D., D.Diab.,
Vice-Chancellor

Tha Tamil Nadu Dr.M.G.R.Medical University

69,Anna Salai,Guindy,Chennai - 600 032.

This Certificate is awarded to Dr/~~Mr/Mrs~~.....R. Kalaimani.....

for participating as ~~Resource Person~~ / Delegate in the Seventeenth (XVII) Workshop on

" RESEARCH METHODOLOGY & BIOSTATISTICS "

FOR AYUSH POST GRADUATES & RESEARCHERS

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 15th to 19th June 2015.

Dr.N.KABILAN, M.D.(Siddha)
READER,DEPT.OF SIDDHA

Prof. **Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.D.SHANTHARAM,** M.D., D.Diab.,
VICE - CHANCELLOR

POST GRADUATE DEPARTMENT OF GUNAPADAM (PHARMACOLOGY)

GOVERNMENT SIDDHA MEDICAL COLLEGE, CHENNAI-106

IDENTIFICATION AND AUTHENTICATION CERTIFICATE

Name of the Student : R. KALAIMANI

Department : PG - SIRAPPU MARUTHUVAM

Batch year : 2014 - 2017

Name of the sample : Rasam (Hydragyram), Gandhagam (Sulphur), Aridharam (Mercuric Sulphide).

Sample description : **Dried whole plant / metal /mineral**

Date of the receipt : 6.6.2016

REPORT

This sample has been critically studied with macroscopic and organoleptic characters along with relevant literature, I declared that this plant/metal/mineral material is correctly identified as Rasam, Gandhagam, Aridharam and I hereby authenticate that the sample given by Dr. R. KALAIMANI.

This certificate issued at his/her request and is given only for dissertation purpose.

Date: 6.6.2016

Place: Chennai

6/6/16

Signature with Seal

Dr. V. VELPANDIAN, M.D(s), Ph.D,
H.O.D - Department of Gunapadam,
Govt. Siddha Medical College,
Chennai - 600 106.

GOVERNMENT SIDDHA MEDICAL COLLEGE
ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE
CHENNAI – 600 106.

POST - GRADUATE- DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN COMPARATIVE CLINICAL TRIAL ON VENPULLI (VITILIGO) WITH THE SIDDHA TRIAL DRUGS *"RASA CHENDHURAM"* (INTERNAL) AND "*PALAGARAI KUZHAMBU*" (EXTERNAL)

FORM I - SCREENING & SELECTION PROFORMA

1.OP NO: ..... 2. NAME: ……

3. AGE: …… 4.GENDER: …… 5. OCCUPATION: ……
6.INCOME:

7. ADDRESS:

……

……

……

8. CONTACT NO: ……

INCLUSION CRITERIA

- Age :18-60 Yrs Yes/ No
- Sex : Both male and female Yes/ No
- Patients having symptoms of Depigmented patches without any structural changes Yes / No
- Patients are willing to give blood and urine for laboratory investigations Yes / No

Patient willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48days but can opt out of the trial of his/her own conscious discretion Yes / No

- Hypopigmentation due to worm infestation. Yes / No

EXCLUSION CRITERIA

HISTORY OF

1. Albinism Yes /No
2. Leprosy Yes /No
3. STD Yes /No
4. Depigmentation due to burns Yes /No
5. Pregnancy and Lactation Yes/No
6. Cardiac diseases Yes /No
7. HIV Yes /No
8. Patients with any other serious illness. Yes /No
9. History of long term use of steroids Yes/No

ADMITTED TO TRIAL

YES ☐ NO ☐

Date:

Station:

Signature of the Guide: Signature of the Investigator:

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FORM II – HISTORY TAKING PROFORMA

1. SERIAL NO OF THE CASE: …… 2.OP NO: .....

3. NAME: …… 4. AGE: …… 5.GENDER: .....

6. OCCUPATION: …… 7. INCOME: ……..

8. COMPLAINTS & DURATION:

7. HABITS OF

SMOKING, YES / NO If yes, specify duration ---------- yrs

TOBACCO, YES / NO If yes, specify duration ---------- yrs

ALCOHOL, YES / NO If yes, specify duration ---------- yrs

8. DRUG HISTORY:

9. FAMILY HISTORY: Whether this problem runs in family? 1. Yes ☐ 2.No ☐

If yes, mention the relationship of affected person(s)

1._____ 2._____

10.DIETARY HABIT: 1.Vegetarian ☐ 2.Non-vegetarian ☐

11. MENSTRUAL HISTORY:

Date:

Station:

Signature of the Investigator: Signature of the Guide:

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FORM III – CLINICAL ASSESSMENT PROFORMA

1.OP NO: ---------- **2.SERIAL NO: ------**

3. NAME: ---------- **4. AGE: ---------** **5.GENDER: ------**

6. DATE OF INITIAL ASSESSMENT: ----------

7. GENERAL EXAMINATION:

1. Body weight [Kg] :
2. Height [cm] :
3. Body Temperature [F] :
4. Blood Pressure (mmHg) :
5. Pulse Rate /min. :
6. Heart Rate / min. :
7. Respiratory Rate /min. :

		Yes	**No**
8.	Pallor :	☐	☐
9.	Jaundice :	☐	☐
10.	Clubbing :	☐	☐
11.	Cyanosis :	☐	☐
12.	Pedal Oedema :	☐	☐
13.	Lymphadenopathy :	☐	☐
14.	Jugular venous pulsation :	☐	☐

8. SYSTEMIC EXAMINATION:

Nervous system ----------

cardiovascular system ----------

Uro-genital system ----------

Respiratory system ----------

Endocrine system ----------

Gastro intestinal system ----------

9. SIDDHA SYSTEM OF EXAMINATION

1. THEGI (TYPE OF BODY CONSTITUTION):

1. Vatha udal
2. Pitha udal
3. Kaba udal
4. Thontha udal ----------

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

1. Kurinji
2. Mullai
3. Marutham
4. Neithal
5. Paalai

3. KAALAM:

1. Kaar kaalam
2. Koothir kaalam
3. Munpani kaalam
4. Pinpani kaalam
5. Ilavenil kaalam
6. Muthuvenil kaalam

4. GUNAM:

1.Sathuvam 2.Raasatham 3.Thaamatham

5. PORI ,PULANGAL (SENSORY ORGANS):

Mei

Vaai

Kann

Mooku

Sevi

6. KANMENDHIRIYAM (MOTOR ORGANS):

Kai

Kaal

Vaai

Eruvaai

Karuvaai

7. KOSANGAL (SHEATH):

Annamaya kosam

Pranamaya kosam

Manomaya kosam

Vignana maya kosam

Anandamaya kosam

8. UYIR THAATHUKKAL: [THREE HUMORS] (VALI, AZHAL,IYAM)

A) VALI

Praanan –----------

Abaanan ----------

Samaanan ----------

Uthaanan ----------

Vyanan ----------

Naagan ----------

Koorman ----------

Kirukaran ----------

Devathathan ----------

Dhananjayan ----------

B) AZHAL

Aamalakam ----------

Ranjakam ----------

Saathakam ----------

Prasakam ----------

Aalosakam ----------

C) IYAM

Avalambagam ----------

Kilethagam ----------

Pothagam ----------

Tharpagam ----------

Santhigam ----------

9.SEVEN UDAL DHATHUS: (7 SOMATIC COMPONENTS)

Saaram

Sennee

Oon

Kozhuppu

Enbu

Moolai

Sukkilam/Suronitham

SIDDHA SYSTEM OF EXAMINATION

1. ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

II .SPARISAM:

III. NAA: [TONGUE]

IV.NIRAM: [COMPLEXION]

1. Vadham 2. Pitham 3. Kabam

V.MOZHI: [VOICE]

1. High Pitched
2. Low Pitched
3. Medium Pitched

VI.VIZHI: [EYES]

VII. MALAM: [BOWEL HABITS / STOOLS]

Niram

Irugal

Ilagal

Others

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Niram

Manam

Edai

Nurai

Enjal

NEIKKURI

Date:

Station:

Signature of the Guide: Signature of the Investigator:

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

POST - GRADUATE- DEPARTMENT OF SIRAPPU MARUTHUVAM

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FORM IV - CLINICAL ASSESSMENT DURING & AFTER TRIAL

1. OP NO: …… 2. SL NO: …… 3.NAME: ……

4. AGE: …… 5. GENDER: …... 6. DATE OF RECRUITMENT: ……..

		0^{th} day	8^{th} day	15^{th} day	22^{th} day
Site					
Size of the lesions					
Number of lesions					
Borders					
Itching					
Depigmentation of Hair					
New lesions appearance					
Repigmentation of Hair					
Colour change					
Regimentation	**Centrifugal**				
	Centripetal				

		29th day	36th day	43th day	49th day
Site					
Size of the lesions					
Number of lesions					
Borders					
Itching					
Depigmentation of Hair					
New lesions appearance					
Repigmentation of Hair					
Colour change					
Repigmentation	**Centrifugal**				
	Centripetal				

Date:

Station:

Signature of the Guide

Signature of the Investigator

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FORM-V - LABORATORY INVESTIGATIONS

1. SERIAL NO OF THE CASE: …… 2.OP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

A) Blood Investigation

Blood Investigations		**Normal Values**	**Before trmt (Date)**	**After trmt (Date)**
Hb (gm/dl)		**M:1215/W:11.5-14**		
T.WBC (cells/Cu.mm)		**4000-11000**		
DIFFERENTIAL COUNT (%)	**Polymorphs**	**40-75**		
	Lymphocytes	**20-40**		
	Monocytes	**2-10**		
	Eosinophils	**1-6**		
	Basophils	**0-1**		
T.RBC(million cells/Cu.mm)		**M:4.0-5.5** **W:3.5-4.5**		
ESR(mm/hour)	**½ hr.**	**M:6-12** **W:7-18**		
	1 hr.			

Blood glucose (mg/dl)	**Fasting**	**70-110**		
	PP	**80-140**		
RFT (mg/dl)	**Blood urea**	**16-50**		
	Serum creatinine	**0.6-1.2**		
LFT (mg/dl)	**Total bilirubin**	**0.2-1.2**		
	Direct bilirubin	**0.1-1.2**		
	Indirect bilirubin	**0.2-0.7**		
	SGOT	**0-40**		
	SGPT	**0-35**		
	Alkaline phosphatase	**80-290**		

URINE INVESTIGATION

Urine investigation	**Before treatment**	**After treatment**
Albumin		
Fasting sugar		
PP sugar		

Date:

Station:

Signature of the Guide: Signature of the Investigator

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FORM VI-INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Date:
Station:

Signature of participant:

Signature of the Guide: Signature of the Investigator

அரசு சித்த மருத்துவக் கல்லூரி

அறிஞர் அண்ணாவினி மருத்துவமனை, சென்னை-106.

மலேரியாபுள்ளி நோயுக்கான சித்த மருந்துகளின் (இரசச் செந்தூரங்கள் மற்றும் பல்லைவர்க் குழம்பு) பரிசோதனை நிறுவனங்கள் மூலம் மருத்துவ ஆய்வறிக்கை தரவேண்டி படிவம்.

முன்னுரை படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இதற்கு ஆய்வாளர் குறித்த அனைத்து வழிமுறைகளையும் நோயாளிக்கு புரியும் வண்ணம் விளக்கியும் மருத்துவர்களுக்கு எனது உறுதி அளிக்கிறேன்.

தேதி :

மருத்துவரின் பெயர்:

இடம்: பெயர் :

உறவு முறை

தேதி : இடம் :

பெயர் :

தேதி : சாட்சிகளின் கையொப்பம் :

இடம் : பெயர்

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FORM VII - WITHDRAWAL FORM

1. SERIAL NO OF THE CASE: ……

2.OP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

6. DATE OF TRIAL COMMENCEMENT: ……...

7. DATE OF WITHDRAWAL FROM TRIAL: ……..

8. REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes/ No
Irregular treatment:	Yes/ No
Shift of locality:	Yes/No
Increase in severity of symptoms:	Yes/No
Development of severe adverse drug reactions:	Yes/No

Date:

Station:

Signature of the Guide Signature of the Investigator

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FORM VIII– PATIENT INFORMATION SHEET

Name of the principal Investigator: **Dr.R.Kalaimani**

Name of the institute: Government siddha medical college,
Arumbakkam
Chennai - 106

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I ,Dr . R.Kalaimani. studying MD (Siddha) at Government Siddha Medical College, Chennai, is doing a trial on the study VENPULLI (VITILIGO). Vitiligo is a common persistent skin disease occurring through the world.

In this regard, I am in a need to ask you a few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study.

Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine Rasa Chendhuram (Internal Medicine- 65 mg BD with palm jaggery for 48

days) and Palagarai Kuzhambu (External Medicine), assuring that you will not be definitely hurt during the course of treatment.

The information I am collecting in this study will remain confidential. I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.

The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.R.KALAI MANI , PG Scholar cum principal investigator of this study, attached to Government siddha medical college, Arumbakkam, Chennai – 106. You can also contact the Member-secretary of Ethics committee, , Govt. Siddha Medical College, Chennai,

அரசு சித்த மருத்துவக் கல்லூரி,
அரும்பாக்கம், சென்னை-106.

மருத்துவ முகாம் சித்த மருத்துவர்களால் (இரண்டு சிகிச்சை
மையம்
பல்கலைக்கழக குழுவால்) பரிசோதிக்கப்பட்ட தாய்மார்களுக்கு மருத்துவ
ஆலோசனைகள் தரவேண்டும்.

ஆராய்ச்சியாளரின் பெயர் : மரு. இரா.கல்யாணி
நிறுவனத்தின் பெயர் : அரசு சித்த மருத்துவக் கல்லூரி,
அரும்பாக்கம்
சென்னை-106.

பட்ட மேற்படிப்பு பயிலும் நான் மருத்துவர்.
இரா.கல்யாணி அவர்களின் முழுமையான மேற்பார்வையில்
நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

அவர்களின் முழுமையான நோயாளி மேல் மேற்கொள் நான்
கொடுக்கும் வரல் இயல்புகள் குறிப்பதற்கு உண்டாகியது. மேற்கொள்
துணை, ரப்பர், பின்னர்பக்க, முதலியவற்றைக்கொண்டு ஏற்படும் மேற்பார்வை
உராய்வுகளினாலும், சில ரசாயன பொருள்களினாலும் ஏற்படுகின்றது.
உடலுக்கு அதனாலச்சையாலும் சில உலோகச் சத்துகள் அல்லது
தான் உபயோக குறைந்த சத்தாய்ந்த உலோகங்களினாலும் உண்டாகலாம்.
இது பார்வ ஊடிய நோய் அல்ல.

இதற்கு ஆராய்ச்சி செய்வதற்காக சில மனிதர்களை
தேடலாம், அதற்காகவும் ஆய்வுக் பரிசோதனைகளுக்கு தங்களை
உட்படுத்தவும் உள்ளனர்.

இது சம்பந்தமாக தங்களது அனுமதி வாய்மொழியாகவும்
ரகசியமாக வைக்கப்படும் என்று உறுதிஅளிக்கிறோம்.

இதற்கு ஆராய்ச்சிக்கு தாங்கள் வருவதற்கும் போக்கு
உட்படும் பட்சத்தில் உள் மருந்தாக இரண்டு மாத்திரை 65
மி.கி.ராம, பனை வெல்லத்துடன், 2 வேளை (காலை, மாலை)
உணவுக்குப் பின் ஏழு மண்டலம் (48 நாட்கள்) உட்கொள்ள
வேண்டும். மேலும் மருந்தாக பல்கலைக்கழக குழுவால் 48

நாடெலுருகு பெரியுளின இடெங்களெலில பிவளெலிலெய தூடவ பேவலெலிடுய. பிவளெலி பெரியாளெலிருகெலி 7 நாடெலுருகு ஜருடுயலெலிறு பருததுலவலெலலாலெலுகு வரிபேவலெலிடுய. இறத ஆராயிசசியால தெங்களெலி அலுயதுதத பிறகு உங்களுருகு வரிருபய இலெலாலெபெலியலாலெ சிபபொது பேவலெலிடுயிளெலிலுய வரெலுகை பெளெலிளெலெலிய.

இறத ஆராயிசசி சமபநதமாக பிறற வரிபரஙகளுருகுய, பெரியாலெ தலைலெய பிறறுயுய, முதலாலெய ஆராயிசசியாளெலிருலெலி பருததுலவர: இரா.கலைலெலியலெலி (பட்ட மெற படிபபாளெலி, சிறபபு பருததுலவ துலைறு) அலுலுகெயுய. லைகபெசி எணெ 7845949200.

மெலுய இறத ஆராயிசசிகு IEC சானறு பெறறபபடடுளளது. இறத பருதது சிறபபாக பிவளெலிபுளெலி பெரியகளை அஙகெரிகபபட சிதத பருததுலவ நுலெலெல வெறபபடடுளளது.

இதுலெல பயலெலிபபடி முதலெய எநத உதலவத பெதாலைகையுய வழஙகபபட மாடடாது.

இறத ஆராயிசசியால பொது, உடலுருகு ஏலறு பாதிபபு ஏறபடுய படசததுலெ அறிகுற அலெலெலி பருததுலவலைலெலியாலெ, தகை சிகிசலைச அளிகபபடுய.

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FORM IX - ADVERSE REACTION FORM

SERIAL NO:

OP NO:

NAME:

AGE:

GENDER:

DATE OF TRIAL COMMENCEMENT:

DATE OF OCCURRENCE OF THE ADVERSE REACTION:

TIME:

DESCRIPTION OF ADVERSEREACTION:

Date:

Station:

Signature of the Guide: Signature of the Investigator:

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